CENTERS FOR MEDICARE AND MEDICAID SERVICES

PRACTICING PHYSICIANS ADVISORY COUNCIL

Hubert H. Humphrey Building
Room 705A
Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

Monday, March 7, 2005
8:30 a.m.

Council Members

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DR. PETER GRIMM
DR. CARLOS HAMILTON
DR. JOE W. JOHNSON
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DR. KEN SIMON, Executive Director, PPAC
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MR. DON THOMPSON, Director
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Center for Medicare Management

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MS. DANA TREVAS, Rapporteur

A G E N D A

Morning

Afternoon

Open Meeting

Dr. Castellanos: I am the chair for the Practicing Physicians Advisory Council, and it's my pleasure to welcome you to this 51st meeting of the Council. I guess before we get started, I have to tell you how this all came about. There's a saying that what a day a difference makes, or what a meeting a difference makes, also. When we had our last meeting, November 22nd, I was council member, I had no idea that we were changing chairmanships and I had no idea anything was happening until I got a very persuasive telephone call from David Clark and Ken Simon. All of you know Ken is very quiet. He's very deliberate. But more important, he's very persuasive. And it was just a lot easier to say yes to him than no. And I got to tell you it's an honor and a privilege to be asked to chair this committee. And with your help, I'll try to do my best. Especially to continue the high standards set by Dr. Mike Rapp. I'd like to make a couple of comments about Dr. Rapp. As you know, he's been a member of PPAC now for almost four years, and he's been the chair of this committee for the last three years. And during his leadership, the Council has really developed an extended and really in my opinion, has done a good job in helping answer some of the questions that CMS has with respect to the practicing physicians. As you know, Dr. Rapp is a practicing physician. He works in the ER. In fact, we talked last night, and he was in the Emergency Room at Bethesda Naval Hospital on Saturday night working a shift. I didn't realize he was an attorney also. He went to medical school. And then after that, went to law school, and actually practiced for about six years, defending doctors and hospitals. And then his wife gave him an ultimatum. He had two out of three choices: either medicine, law, or the family. So I think he picked the best two choices. Mike, I wonder if you could stand and give us some words of wisdom and share with us what you're going to be doing and tell us what you're going to do with all your free time that you're going to have.

Dr. Rapp: Well, briefly, the big change in my life is I've accepted an appointment with CMS to start in two weeks from today, actually, in their Office of Clinical Standards and Quality. So I'll be working with Trent Haywood who will be here later. So, for me it's an exciting opportunity. It's an important area, I think, that the agency's going to be involved in so. At any rate, the opportunity and offer came, and I took it and I'm looking for it. And so, thank you for your kind words and I know, having worked with you for the last three years, you're going to do a great job as chair and I'm looking forward to all the advice you give the agency, and hopefully I'll have some continuing interaction with you.

Dr. Castellanos: Great. Again, thank you, Mike. And we really wish you the best in your new endeavors. We're going to look forward to hearing from you and one of the Council recommendation is going to be that continue to pick out the restaurants on Sunday nights for our dinners. That's an outstanding job that you've been doing.

Dr. Rapp: Thank you.

Dr. Castellanos: Mike, as you know, is going to be a great addition to CMS. And the important thing here is they're using practicing physicians, like Bill Rogers, who is still working as an ER doctor, Dr. Haywood, who is an internist, works as an ER doctor, and Mike Rapp. Seems like CMS has a lot of ER doctors, don't they? I would like to thank all of you who made it here today. We're looking forward to a very productive meeting, and a discussion on some of the issues relative to the various Medicare Programs. This is really an exciting time that we're dealing with. A lot of challenges in addressing some of the issues in our health care delivery system. And we welcome all of you here, and thank you for being here. At this time, I would like to ask Mr. Herb Kuhn, Director, Center for Medicare Management, Centers for Medicare and Medicaid Services to welcome you.

<u>Welcome</u>

Mr. Kuhn: Thank you, Dr. Castellanos, and let me also extend my heartfelt thanks to Dr. Rapp for his leadership and his chair during the time of PPAC. It's made my job a lot easier to have you here. And thank you for your stewardship of this committee when you were chairing it. Also, I think the whole committee looks forward to the time hopefully in the not too distant future when you'll be sitting at that table making a presentation to us, in terms of an issue, and get to see what it's like from that side. We welcome you to CMS. We're mighty lucky to have you part of the team here, and we're looking for great things there. Also, to Dr. Castellanos, thank you for stepping up to the plate and assuming this role as chairmanship. We look forward to your leadership. Just to let you know that Dr. Castellanos and I had a chance to chat last week as we prepared for this meeting. I really like his ideas. I like how he wants to continue to work forward on the improvements we've made with the committee, so I think it's going to continue to make it a richer and fuller experience for all of us. And we're pleased for your leadership, and thank you for that. Finally, let me just make an observation about kind of where we are and what we hope to be able to track this year as part of PPAC on a go-for basis. I think over the last several years, under Dr. Rapp's leadership, we've tried to make this experience much better, not only for CMS, but for all of you. You're all making a major commitment here. You're committing for four times

a year to come to Washington to participate in this effort, and it's a valuable experience for us. We hope it's a valuable experience for you as well. But how can we make that better? I think over the last couple years, we've tried to do that better in terms of getting information to you sooner, as part of the process. Many of you'd expressed an interest. The fact that you'd like to do some research on some of the issues earlier in the process, be it search the web, talk to your colleagues, etc., and hopefully I've fulfilled that request by all of you to make sure that we have that information to you sooner. Likewise, I think we've been able to create more time in the discussion areas so we can get as full and complete a discussion as possible, with real focus on the issues that not only CMS wants to hear, but also focus on the issues that you want to make sure that we hear as well, from both sides. And then finally, what I think we've also been able to accomplish over the last couple of years is not only deal on what's the here and now, but also talk about what's in the future. And help us do the horizon scanning with you, to help us sight some of the issues and some of the things that we'll be addressing out there earlier. And I think today is a good example of that on at least a couple of issues that we have forward; the Competitive Acquisition Program for Part B drugs is one that we have a Reg out there to get your thoughts and comments today will be extremely useful. And of course the discussion we'll have this afternoon with Dr. Trent Haywood on Quality and Payment for Performance. I think are definitely issues that fit that category. But as we begin this year, we've had a chance of staff to kind of talk to our colleagues within CMS again, to see what more we can do to add to this experience, not only for you all, but for us, particularly in this area of Payment for Performance and as we move in this area. And so we've had a lot of extensive conversations with our colleagues at the Office of Clinical Standards and Quality, and also ORDI, the Office of Research, Demonstrations, and Information. To have them be active participants in this process as well, and come in to make presentations for you to talk about these issues, and so, I don't want to predict exactly all the issues for the rest of the year, but I have a good suspicion that at least each and every one of the four meetings we have this year will have at least a good detailed discussion on Quality and Payment for Performance. Because it's here, it's now. It's no longer flavor of the month. It's the issue of the day for many of us to work on. And we hope to take full advantage of your experience out there for part of those discussions. So again, thank you all for your commitment, your continued commitment, and we look forward to a good day of meetings. Thanks.

Dr. Castellanos: Thank you, Mr. Kuhn, for those welcoming remarks. And we appreciate you being here and we certainly appreciate Dr. Thomas Gustafson for being here, also. I know it's a lot of time out of your

schedule. You guys are very very busy, as I found out last week, trying to contact you. You have your plateful, and we certainly appreciate you both being here. At this time, I'd like Dr. Ken Simon, Executive Director of the Practicing Physicians Advisory Council, for Medicare Management, to provide us with the update on the November 22nd Recommendations of the Council, and the Center for Medicare and Medicaid Service's responses.

Update

Dr. Simon: Thank you. Just prior to reviewing the recommendations from the November 22nd meeting, I'd just like to echo the comments that Mr. Kuhn made, that over the last year and a half, I've enjoyed the opportunity to work with Dr. Rapp as we have put these meetings together, and more importantly addressed issues that are of concern to physicians that are taking care of patients, Medicare beneficiaries, Medicaid beneficiaries, throughout the country. And so I look forward to working with you, Dr. Castellanos in that regard.

The minutes from the November meeting, Agenda Item D-1. PPAC applauds CMS for approving additional funding for all carriers who requested funding a part-time staff to clear the backlog in physician enrollment applications. The new enrollment backlog, which peaked at 45,712 in April 2004, is now below 20,000 as of January 27, 2005. Reassignments peaked at 44,667 in April 2004. And now dropped below 11,000 on January 21, 2005, which is below the historic norm of 13,365 in December of 2004.

For Agenda Item F-1. PPAC recommends that CMS specifically identify all the data sources it uses for determining the update for professional liability RVUs. CMS specifically used specialty specific malpractice premium data for the top 20 Medicare physician specialties measured by total payments. Premiums were for 1,000,000 class 3 mature claims made policy, which is the policy that covers claims made rather than services provided during the policy turn. We attempted to collect 2000 and 2001 premium data from all 50 states, Washington, D.C., and Puerto Rico. Data were collected from commercial and physician insurers, and from joint underwriting associations. The premium data that we collected from the private insurance companies had to match the market share data that were provided by the respective state departments of insurance. Because none of the state departments of insurance had 2003 market share information at the time of this data collection, 2003 premium data were not usable, and consequently, 2002 data was used.

For Agenda Item F-2: PPAC recommends that CMS institute a process to receive information from physicians from all specialties if they're unable to purchase drugs as ASP (average sales price), as well as a

process to institute changes in the ASP before the end of the quarter and to make those changes retroactive to the beginning of the quarter. CMS's response is physicians should work with their specialty societies to identify drug suppliers with optimal prices. For example, ASCO has committed to working with this membership on this issue. A recent ASCO survey of drug acquisition costs indicated that lower prices were not necessarily dependent on practice size. They are identifying purchasing strategies of these smaller practices. We expect that other specialty societies are similarly committed to helping their membership on this issue. While CMS receives data from individual drug manufacturers on average sales prices, we are prohibited by law from disclosing this data at the national drug code level. The law requires that the Medicare payment is based on the average sales price, plus 6%. On the issue of mid-quarter changes, the law requires quarterly reporting and price updates.

Agenda Item F-3: PPAC recommends that CMS discontinue the least costly alternative policies as they do not comply with Congress's and CMS's express desire to let market forces determine average sales price. Least costly alternative policies are local coverage determinations, commonly called LCDs. These policies follow the public process associated with all LCDs, and are based on clinical evidence. If physicians in a local area believe that the clinical efforts on which a local coverage determination is based is no longer valid, CMS encourages active dialog between the local carrier and the local physicians on the evidence.

Agenda Item F-4: PPAC recommends that CMS investigate carriers' poor application of least costly alternative policies. The response: CMS is continually monitoring carriers' performance of all their responsibilities. While one carrier did experience a claims processing issue surrounding a local carrier determination, involving at least one least costly alternative policy, the carrier has corrected the problem. We are unaware of any current claims processing issues surrounding local coverage determinations involving least costly alternative policies.

Agenda Item F-5: Because CMS has already compiled a list of drug prices by manufacturer to determine average sales price, PPAC recommends the list be published on the CMS website so physicians can use the information to purchase drugs under average sales price. The CMS response: Due to the proprietary nature of the average sales price data, the law prohibits this disclosure at the level recommended by the Council.

Agenda Item F-6: PPAC recommends that CMS and the Office of the Actuary compare and contrast the factors in the MEI and the market basket, to explain why the same index cannot be used for both physicians and hospitals. CMS Response: Section 1842, B-3 of the Social Security Act details the requirements of a Medicare

Economic Index. Specifically stating that it be developed on the basis of appropriate economic index data. That such higher level is justified by year to year economic changes. The MEI, both as it is currently defined, and in prior versions, reflects the cost structure and price changes associated with the inputs used in providing physician services. Section 1886, B-3, i-3 of the Social Security Act requires the development of a hospital market basket that is based on the index of appropriately weighted indicators of changes in wages and prices, which are representative of a mix of goods and services, included in such inpatient services. The hospital market basket, therefore, reflects the cost structure and price changes associated with the inputs used in providing hospital services covered under the inpatient hospital prospective payment system. As such, CMS and the Office of the Actuary feel that it would be inconsistent with the legislative requirement as well as technically inappropriate for the Medicare Economic Index, and the hospital market basket, to be defined similarly. For the Council members inside your folder, there is a document that's labeled Outpatient Prospective Payment System Update. That form, which should be on the front of your binder, outlines the factors that influence the various payment systems. The inpatient payment system, the outpatient payment system, and the Physician Fee Schedule.

Agenda Item F-7: PPAC recommends that CMS expand the criteria for participation in the one-year demonstration project on cancer treatment to include the types of chemotherapy, whether it's subcutaneous and intra-muscular infusion, intra-vesicle application, and surgical implants, in addition to push and infusion methods. The one-year demonstration project is a limited scope study that's designed to evaluate the impact of monitoring patients' symptoms related to chemotherapy administered through the push or infusion technique. We believe that the one-year cancer demonstration project is a valuable experiment in improving the quality of cancer care provided to Medicare beneficiaries. However, we think that it is premature at this time to discuss expanding the scope of the demonstration project until we have adequately evaluated the current project data. By limiting the study to the methods of chemotherapy administration selected, we are better able to control for other factors that may affect these symptoms, i.e., longer infusion times associated with implanted pumps.

Agenda Item G-1: PPAC recommends that Medicare provide to physicians a MedLearn Matter article simplifying the concepts of observation versus impatient admissions that will improve the physicians practices in admitting patients to hospitals. CMS is currently reviewing several issues related to physician orders and patient status in the hospital setting. Once these issues are resolved, CMS will develop a MedLearn Matters article that summarizes Medicare policy related to observation status and inpatient admission.

Agenda Item I-1: PPAC requests that the DOQIT project work with the OIG or the General Counsel to find measures that can legally protect physicians when information is gathered under the Quality Improvement Activities. The CMS response: The patient information contained in an electronic health record, and submitted to the quality improvement organizations, commonly called QIOs, would not be discoverable in malpractice actions. By law, such information is already protected from discovery and such actions.

Agenda Item I-2: PPAC requests DOQIT provide guidance for levels of security required to avoid infractions under HIPAA. The CMS response: To ensure compliance with the Privacy Rule, privacy when using medical records, from a Privacy Rule perspective, one must merely ensure that they have reasonably safeguarded and protected the healthcare information from any unintentional or intentional use or disclosure that is in violation of the standards, implementation specifications, or other requirements of this sub-part. And one would have to refer to the statute that's listed here. From the security rule perspective, the security rule requires covered entities to assure confidentiality, integrity, and availability of all electronic protected health information. The entity creates, receives, maintains, or transmits. Covered entities must protect against reasonably anticipated threats or hazards to the security or integrity of this information, as well as reasonably anticipated but impermissible uses and disclosure of the electronic health information. The security rule was written with the recognition that each covered entity is unique and varies in size and resources. Consequently, to achieve these requirements, a covered entity may use security measures that are reasonable and appropriate in its environment, taking into account its size, complexity, capabilities, the cost of security measures and the probability and criticality of potential risks to the electronic health information. HHS recently issued additional guidance on the security rule and it can be found on the HHS website, and that information is contained on the HHS website under the HIPAA security rules.

Agenda Item J-1: PPAC recommends CMS pursue multiple avenues to educate beneficiaries new to Part B Medicare about the Welcome to Medicare Exam benefit, and its limitations and rules. CMS response: CMS has developed and is continuing to develop external communications/collaborations to make beneficiaries aware of the new preventive benefit. These include information in Medicare in Year 2005 Handbook, the revised booklet, the Guide to Medicare's Preventive Services, multiple fact sheets, including one that will be translated into fourteen languages. [off mike: Including Farsi!] A bilingual brochure for Hispanic beneficiaries, use of various community based outreach and educational programs, and many other means of educating the public

through CMS websites and at 1-800-MEDICARE toll free help line. Regional offices, the state health insurance assistance programs and partners at the national, state, and local levels. CMS is also working on the developing of an outreach tool kit to be used early in 2005 in public town hall meetings by members of Congress that will include messages on the new preventive benefits. Local promotion materials, including public service announcements, drop-in articles, and flyers are also available at this time. In addition, the Provider Communications Group, within the Centers for Medicare Management, insures that physicians and other health care professionals are informed about the new preventive benefits and are prepared to assist Medicare beneficiaries in obtaining these new services, such as 1. an initial preventive physical examination; 2. cardiovascular screening; 3. diabetes screening test; and the agency believes that the provider community plays a role in helping CMS ensure that all beneficiaries receive these services when appropriate. The CMS staff will attend cross-agency meetings and conferences of provider organizations and professional associations, to ensure coordination, consistency of content, language, and incorporating core messages into beneficiary related information.

Agenda Item C-1: PPAC recommends that CMS format the presentation of the PPAC recommendations and responses similar to the format used by PRIT and that the recommendations and responses be made available to PPAC members prior to each PPAC meeting. The response: CMS will make every effort to respond to the Council's recommendations by the subsequent meeting date. Once the responses are completed, reviewed, and cleared by the agency, CMS will make them available to the Council members.

Agenda Item O-1: PPAC recommends that CMS provide the discussion materials for agenda items at least 3 weeks prior to the PPAC meeting, to allow for preparation and self-education by Council members. CMS recognizes the importance of the Council members' having access to the discussion materials as early as possible, in order to be prepared to provide appropriate input relative to issues and policy decisions. CMS is committed to providing the agenda and the discussion materials in as prompt and timely manner as possible. And we hope that, at least with this meeting, we met your expectations.

That concludes my report.

Dr. Castanellos: Thank you, Dr. Simon. Are there any comments or questions from members of the Council? Dr. McAneny?

Dr. McAneny: On the recommendation F-6, the concerns that we expressed last time was to get a little more detailed than this. I remain unconvinced, actually, about the MEI and the market basket, since the MEI, since the market basket, every time you look at the hospital updates, it's 3.8%, and MedPac has recommended again that it go on up, whereas the Physician Fee Schedule continues to get cut. I think a lot of the differences are that when this was written, hospitals did everything as an inpatient, and physicians' offices had a doctor with a stethoscope and his wife with a pegboard doing the scheduling and there really wasn't much in the way of practice expense. And that's just not the way of the world now. The hospitals are doing outpatient services that directly compete with what the physicians are doing, physicians are hiring the same numbers of high-tech employees as the hospitals are. We're hiring radiation techs, and we're hiring chemotherapy nurses and we're hiring operating room assistants and we're hiring X-ray techs, pretty sophisticated personnel, plus we now have the same type of overheads. Many of us are hiring CPAs, and we're continuing to use the exact same personnel on a national market that the hospitals are. The only thing that the hospitals seem to have to do is to buy bed linens and food, and if you've eaten in a hospital lately, you know they aren't spending a whole lot of money on that. So I think there still is a major discrepancy between what the hospital gets as its average market basket update and what we can get. And we pay the same prices for the services we do. So I would like to send that one for more detail, in terms of I would like to hear, as the market basket—I would like to see the two items taken apart, so that we get a discussion of what are the factors that are in the market basket, and how do they differ from what the factors are in the MEI? Why do we get labor force numbers and they get the personnel for nurses, etc., that kind of level of detail.

Dr. Castellanos: Are there any other questions for Council members.

Dr. Gustafson: If I could respond to the first comment, just for a moment. We can certainly provide a more detailed rack-up of exactly what the two indices look like. They are different. They do reflect the input uses in the two different sectors. And the Office of the Actuary does update them regularly. So I understand Dr. McAneny's points about physicians' offices being a good bit more sophisticated than they once were. I believe if we disentangle this at that level, you will discover that that secular change has been reflected in these indices as they've evolved over time. But the central point of why you are seeing different outcomes applicable to hospital outpatient departments or hospital inpatient departments first as physicians, is what is described on the sheet, which is a little bit, the title of which is not necessarily entirely revealing—Outpatient Prospective Payment

System Update. I asked my staff to prepare this in response to the discussion we had at the last meeting. The central point is not the difference of the indices. I mean, we'll explain that. Be happy to show you all that information; there's nothing to hide here. The central point is that physician payment updates are subject to the SGR, so the target comes in and affects what's going on. That is not true in the hospital. There is actually a provision in the law for an SGR-like apparatus for hospital outpatient departments, but that has never been implemented. So I think once we disentangle this, you'll see that the indices give you a fair shake, and the target of your concern ought to be the nature of the SGR and how things happen after the index gets done, in order to squash down the update.

Dr. Castellanos: Thank you. Are there any other questions. I have two comments. The first is on the issue of F-3, LCA. I guess what I was asking, because I made that presentation, was that today we have five states that don't use LCA. We have Utah, which just went on a 6-month program where they're testing whether they need LCA or not. And I think what the practicing physicians, at least in my specialty, want is a level playing field. Now whether we have LCA or not is not the issue. The issue is I think it's important that every physician have the same level playing field. And I know I talked to our local carrier medical director, and I mentioned that to him. And what he was hoping for is maybe a national directive. Now that's just a comment, and I don't anticipate your following up anymore than taking my comment, but it is a difficult situation when I'm practicing and getting reimbursed differently than maybe six other states' physicians.

Dr. Gustafson: You're right. You're describing the current situation accurately. Least costly alternative is used by different carriers on different drugs or not at all. It is a decision which resides with the carriers at present. So we do not have the authority under our current regulations to do least costly alternative at a national level. You may want to consider whether you want that or not. It's a two-edged sword. Consistency is obviously to be desired. Responsiveness to local medical conditions is also to be desired, so there's a two-edged sword attached to that. And there's the question of the least costly alternative on a national level is one that might have some controversy associated with it. Whether the consistency is worth that is a different question.

Mr. Kuhn: It's something to think through just a little bit further on that. As Gus gives his presentation here, shortly, on contract reform. Think about this in the total context as we move from the current patchwork we have out there in terms of FIs, carriers, etc., and we move to the new world of Medicare Administrative

Contractors, known as MACs, something to think a little further about in that context as we have that discussion, is a possibility.

Dr. Castellanos: Just one other comment on Quality Initiatives, I-1. In Florida, we unfortunately just had three constitutional amendments. And one of the constitutional amendments was to open up the peer review system, the quality care system, and make these discoverable. Now, obviously this is a point of contention, and I'm sure it'll go through the court system. But in Florida, in November election, this material, based on the constitutional amendment is now discoverable in our state. And I want to make sure you're aware of that.

Dr. Gustafson: I think we will take that back with our QIO folks. You can see, Doctor, the comment that was in the matrix here is from Dr. Bill Rollo, who is in charge of this area. And I think what would matter there is the extent to which federal law is what's driving what Bill had to say here, in so far as that's true, that would nominate even a constitution in Florida. But I don't in fact know what the answer to that is. We'll generate some more information on that point.

Dr. Castellanos: Thank you. Are there any other further comments or questions? Dr. McAneny?

Dr. McAneny: Just two. One is that on the first item, it's great to have the backlog down that far. I'm hoping that with the efficiencies that the agency has learned on getting people re-registered that we'll start to see that it takes less time to get new physicians their Medicare numbers. That would really be nice. It's still taking us six months for a new DOQ to get them able to bill Medicare, which is a tough thing for cash flow for the practice. And on the ASP issue, we've already had a situation where after ASP came out for January, the manufacturer's price went up for, as far as we could find in any manufacturer. So the price of a certain drug is now higher than the ASP for January, yet we're stuck purchasing that drug all the way through 'til hopefully it gets revised at the end of March. Which means, for a large practice, where we can buy in bulk at the beginning, that we're going to be OK. But for a small practice that mostly buys chemotherapy at smaller increments and therefore has to get the drug at the higher price, they're going to be taking a loss every time they give that drug, regardless of administration, all the way through that quarter. For smaller oncology practices, and most oncology practices are still one-, two-, or three-physician groups, they're not going to be able to afford to do that and I hear a lot of colleagues already discussing how they can ethically, it's impossible to not give a given drug to a patient when it's their indicated need. But when you take a hit on every single dose, it really puts you in a bind. And so there are a lot of smaller groups that are really struggling with that, just as a point of information.

Dr. Castellanos: Thank you. Are there any other comments? Dr. Simon, again, thank you for your points. At this time, Dr. William Rogers, Medical Officer to the Administrator, Center for Medicare and Medicaid Services, will provide us with an Update on the Physicians Regulatory Issues Team, better known as PRIT. In his presentation, Dr. Rogers will discuss some 20 issues with the status updates. He's also going to provide us with some detail on his speaking engagements and we hope some good cartoon jokes.

PRIT Update

Dr. Rogers: Thank you. This is a pleasure for me to speak to you all. We had a late breakfast this morning and got caught up on what's going on in our various lives. You didn't give me an assignment this quarter, which made life easy. We've sort of just been taking it easy for the past three months. But that may change after this meeting. As you mentioned, I'm going to talk a little bit about the issues that we're working on now and some of the speaking engagements that are coming up. But first, as the owner of a cat and a dog, I really like this cartoon. [laughter]

A couple of oncology issues. I just went last week and spoke to oncology practice managers, and I found that they seem to care a lot more about their doctors' dollars than the doctors do. They were as aggressive a group as I've ever addressed in two and a half years. And they have a lot of concerns obviously about ASP and about infusion codes and things like that, and we had a very interesting dialog. But a good lunch after it. The first one is the issue about the chemotherapy push and they're concerned about this issue of continuous presence. I used to know what a chemotherapy push is and I realize now that I don't anymore, because we have sort of changed the definition, but there is a concern if you've got an infusion of 25 minutes, the issue of continuous supervision. So Ken took the concerns to the CPT Editorial Committee and we're working on resolving this as quickly as we can. Another issue that doctors are really concerned about is recovery audit contractors. This could be a great thing for the taxpayer, and a great thing for the Medicare Program, but doctors have said to us that their concern, since the contractor's going to share in the money that's recouped that there is an incentive there to be very aggressive. So we're going to help make sure that concerns are heard by those who run the program.

Competitive Acquisition Program I think is going to be a great step forward, particularly for people like rheumatologists and neurologists, who don't do as much infusion as oncologists do. And there's going to be a nice option, but there's a lot of moving parts and doctors are constantly saying to me, what'll happen if the white count's too low, and I have to get some infusion, or if the dose that's delivered is wrong and things like that. And

it's going to be complicated. I mean the auto manufacturers doing this just in time stuff, and I don't see any reason that we can't do it, too, but we're going to have to make sure that we know about all the potential complications as we develop the program. There will undoubtedly be some growing pains as we start working on it. But I think it's going to be a useful option for physicians for whom infusion is not a main business. The other two issues are sort of in the weeds issues that we got resolved.

Co-signature requirements in a critical access hospital. This was an issue that was brought to us by physicians assistants. It came from a change in our interpretive guidelines, and we've I think resolved it to everybody's satisfaction and should have an update on the website in a day or two, but that resolution was publicly announced.

CMS official letter to beneficiaries. This would sort of harken back to an issue that was with the PRIT when I joined the PRIT, an issue of a letter which was a little bit too accusatory in its language, and physician—well actually a representative of the medical societies brought the letter to our attention, and we were able to get it rewritten in a more balanced format.

These are sort of in the lead issues, The modifier pap smear screening was a really important issue. It had to do with statutory limitation and frequency and we were able to come up with, dialoging with an oncologist and with our physician payment staff, come up with a good resolution that everybody was happy with. Lot of arranging of dialog and things like that but it's always better to get these things talked out to everybody's satisfaction.

On this slide, the cardiac rehab supervision is a big issue for a lot of physicians, Dr. Urata's had a lot of concerns about this, and we're working on making sure that your concerns are heard. We're still waiting for an OID report, and we really can't change anything until this OIG report comes down. That's sort of the hold up on that.

Mental health treatment limitation has been frustrating, too. And we're having trouble getting traction on this for a lot of reasons. I think it would take 45 minutes to talk about why this has been difficult to resolve. We're making sure that particularly geriatric psychiatrists, we spoke to them this past weekend, their cares and concerns are being heard and that we're trying to get this resolved in a positive way.

Macros is also an issue that's been difficult to get everybody to agree on, but we're still working on that progressively, pushing to get that resolved.

Post anesthesia reports has been resolved in good way. Now any member of the group can do the post anesthesia report. It doesn't have to be done by the anesthesiologist who administered the anesthetic, which certainly simplifies life, particularly for the larger practices.

Verbal orders is waiting for the conditions of participation which are going to be released imminently.

Pretty good cartoon. If you can't read it, the fellow holding the pistol, says, "Damn, I forgot to say you're fired." That's me inside the door after this report.

We've added a couple of codes, couple of issues, since we did this speech, and something having to do with some physicians who appear to be in the [hipsa?] area and it created a huge problem for them because they weren't. So they were submitting their claims and then getting the claims rejected. And it was just a matter of getting a zip code corrected. But we got that done very quickly. The staff jumped on that and got it fixed very quickly. And then there's issue of the average sale price that was mentioned here. As I go out and speak to rheumatologists and oncologists, I'm constantly being handed little slips of paper with funny prices on them and so I'm bringing them back to our staff, who fix those things. And they're looking at the entire list of ASPs because there were some funny numbers that crept into the list and we want to get them fixed just as quickly as possible.

These are just, some of this is actually three weeks old, and we've added a couple more speeches since then. In fact, I just was Blackberrying an acceptance of a speech to the rheumatologists next November, but basically you can see we're out talking to a physician group about once a week. But we're not going to have to do this for long, because we are constantly getting to the PRIT website these offers. And this particular one alone has made Robert, Jackie, and me $2,550,000, and pretty soon my bank's not going to accept any more money, so if anybody wants me to forward these to them, I'll be glad to.

So that's my phone number. That's the phone that's on my hip. That's the email address for the Blackberry that's on my other hip and I look forward to new issues and new challenges as we move forward.

Dr. Castellanos: Thank you, Dr. Rogers, for that presentation. You really covered a lot of material and you're certainly busy with your speaking engagements. Do any of the Council members have any questions for Dr. Rogers? Dr. McAneny?

Dr. McAneny: I don't know if this is the right time to talk about the push versus the infusion, but you brought it up so I will. This has been a big issue and to me, I do not frankly understand what all the fuss is about.

I'm old enough that I gave a bunch of chemotherapy before they decided that medical students and residents and people couldn't do it, and so I now I supervise nurses doing it. But if you have a push, you have the drug in a syringe, you have an IV line in somebody's vein, and you sit there and you're looking at it. Because if it's a vesicant, and it extravasates, you have a third degree burn in somebody's arm which is a bad thing. So you sit there and you're looking at it constantly while you push it. And a push can be a slow thing because I learned very early as a medical student that if you take Adriomycin and you go whoosh, and push it in, the patient throws up in your lap. So you sit there and you give it very slowly, but you're sitting there at the bedside with your hand on the syringe. A short infusion, on the other hand, you put in a little plastic baggie, you drip it in, and often what happens is we'll drip those in and the nurse will start the first one and then go mix the other drugs to bring them back to that patient so she's not sitting there gazing lovingly into the eyes of the patient while the IV is just sort of dripping in by gravity. Yet there's all this commotion about what is a push, and what is a drip. And to me, if you just go to the reality of what you actually do, there shouldn't be an issue. They are two different procedures. And nobody can afford in this day and age to have an oncology nurse sitting at the patient's chairside, watching a drip go in for half an hour and being in constant attendance. Whereas with a push, you have to because your finger is on the syringe pushing it in. So I would like to relay back to you or to whomever the appropriate people are, that what they need to do to figure out this issue is just to go to an oncology/chemotherapy center and watch what they do. And they'll see the difference between the two procedures right away.

Dr. Rogers: I'd reply with a question. If the CPT Editorial Committee were to change the wording so that the constant attendance was no longer required, would the sort of arbitrary 30-minute definition be OK, if we kept that?

Dr. McAneny: You mean to have anything—

Dr. Rogers: Anything less than 30 minutes being a push, and anything more than 30 minutes being an infusion, just sort of as an arbitrary way of defining one versus the other? Because we have to obviously distinguish between the two.

Dr. McAneny: You need to distinguish between the two. Obviously you don't want to have the constant attendance there for an infusion, so yes, it would help immensely to get rid of the constant attendance idea. But they are two different processes. So an infusion can take 15 minutes to just drip in if it's a Premed or Benedryl or

Decadron or something like that you can just drip that in. And you don't have to be in constant attendance and there's no reason to be. But a push is a different thing, so I don't understand why the CPT Editorial Committee wrote it the way they did. Getting rid of the constant attendance would help, but they are two different things.

Dr. Rogers: Do you know who your oncology rep is?

Dr. McAneny: Yes, they tried.

Dr. Simon: Mr. Chairman?

Dr. Castellanos: Yes?

Dr. Simon: I'd just like to add additional input, I think it would be helpful, Dr. McAneny, if you would chat with the representatives that represent your specialty society. I think you should be comforted to know that your representatives actively participated on the CPT Panel in helping to create the definitions that are currently at play. And I think that probably at the time that the definitions were created, to be fair to all, I think that they probably didn't realize operationally what the outcome would be. But having said that, your representatives were there and actively participating throughout the entire process. I think that the Editorial Panel is aware of the concerns as it relates to the practical practice of medicine and the work group in fact, has aggressively dealt with this issue at the last CPT Editorial meeting. And so I would envision that changes will be forthcoming. The ASCO representatives were also actively participating in the work group as well, so that the Panel did rely on their expertise in helping to develop the language that's been put in place. I just wanted to share that with the Council.

Dr. Castellanos: Dr. Urata?

Dr. Urata: I just had a question on Recovery Audit Contracts. Can you explain what that is?

Dr. Rogers: I'll try. My understanding is that there are contractors who will look at Medicare claims and fine claims which were inappropriately paid and the monies which are recovered then will mostly return to Medicare, but a percentage will be paid to the Recovery Audit Contractor. It's a three-state demo to see if it's a helpful addition to our current efforts to prevent fraud.

Dr. Urata: And this is based on [?] audits?

Dr. Rogers: I'm not sure that we know the breadth of things, the tools that they'll be using to discover these. . .

Mr. Kuhn: This was a provision that was in the MMA. And it's one that we're working with our Office of Financial Management to begin moving forward, as I think he said in the report, that's going to be offered in three areas initially and go forward. I think we'd like to get with our Office of Financial Management perhaps to get you more detailed information on that. We can get that for you.

Dr. Urata: I think it would stand as kind of a widespread thing. Everybody would like to hear more about it.

Dr. Castellanos: Dr. Senagore?

Dr. Senagore: A comment on the status of First Assistance. And there is language now through CPT on how that is done. Is the issue on the Regulatory side?

Dr. Rogers: The issue as it was brought to us was by a physician in a teaching hospital, who sometimes is doing very complex surgeries and only has general surgery residents. And in these complex surgeries, I believe they were vascular surgeries, our requirement that you use a resident if a capable resident is present. I forgot the exact wording. Was a little unclear to him as to whether that meant that he had to use a resident or whether in these complex cases, it would be OK to say that there is no resident who's competent to assist me and therefore I can use my partner or something like that in the procedure. And so what we're trying to do is bring some clarity to that situation.

Dr. Senagore: Yes, because I think the language in CPT is accurate. It's going to—where the rubber hits the road is what the word "qualified" is going to mean.

Dr. Rogers: Right. That's right.

Dr. Castellanos: Dr. Johnson?

Dr. Johnson: Would the Recovery Audit Contracts, that's still slated to begin in May of '05? Have the three states been chosen?

Dr. Rogers: Yes, they have been. New York, California, and Florida.

Dr. Castellanos: Are there any other questions? Dr. Rogers, again, thank you for your presentation. The chair, being a urologist, fully recognizes a need for breaks. [laughter] We're definitely going to take a break. Why don't we take a 15-minute break and try to be back here about ten minutes to ten.

Dr. Castellanos: Everyone please take their seats, and I will resume the meeting. Because of some scheduling changes, it's important that Dr. Gustafson present now. He's going to have to go up on the Hill this afternoon, and Mr. Kuhn said it was either he or Dr. Gustafson going up there, and. . .[laughter] I don't think that's much of a question about whom he picked. Dr. Gustafson's going to give us the report to Congress on the Contractor Reform. As you know there's a tremendous interest now in this report and it'll be presented by Dr. Tom Gustafson, Deputy Director Center for Medicare and Medicaid Management.

Report to Congress on Contractor Reform

Dr. Gustafson: Thanks very much. I'm going to just sit here, if that's OK with everybody. I'm going to launch right in here. One of the significant responsibilities of our Center is running the contractor network, so that the Fee for Service program pays about a billion claims a year, and that's done through our existing network of FIs and carriers. And in a development which goes back at least a decade, we have been trying to figure out how to essentially move into a new world in this. Much of the existing structure of the contracts and contractors goes back to the origins of the program in 1965. So we're about modernizing this entire enterprise. And I'm going to lay out a little bit of the detail about this and tell you about our report to Congress and so forth. On the next slide, we show the goals that we've articulated for contracting reform. And among the important elements here are to try to achieve a situation where the various entities, basically us and you, are working together more smoothly and more cooperatively. Introducing competition is an important element in the how we are choosing contractors. If you look around, our existing contractors, many of them have been there essentially in perpetuity. We have not had any regular system of revising the contracts, of choosing new contractors. There's a comfortable old shoe aspect of this in some respects, but it hasn't necessarily achieved the degree of performance that we would all like to see. And we want to be able to provide incentives to these contractors so that they will not only compete for the business, but be rewarded when they do the business well, and this is the kind of thing that I think many of you might think of as, Gee, doesn't that make sense? How come we're not doing it that way now? Well, the answer is until this year, our statute hasn't afforded us the ability to do that.

The statute came along, §911, we try not to regard that as an icon or a talisman here, but §911 of the Medicare Modernization Act that passed in December of '03 provides an entire section relative to contracting reform. And the slide here shows you the major elements of that. First is the integration of A and B contracting. We'll have a new entity which is called Medicare Administrative Contractor, which will handle both of those

lines of business. There is some subtlety to that. I'll come back to that in a little bit. The contracting will occur under something called the Federal Acquisition Regulations, or FAR, you will hear people talk about FAR-based contracting. That's the standard way that the government buys desks or missiles. We up to now have been using a specialized authority that is in Title 18, it's called Title 18 Contracting Authority. Which has some peculiarities including the ability to have these essentially perpetual contracts. But we will move into a more standard world where things are competitively bid and you can see the timeline that's shown there, the statute provides us a six-year period to transition all of this work. You need to think of this as kind of an ocean liner. We don't exactly turn on a dime. We've got a million give or take providers that bill us. Most of them are physicians, but there are 250,000 other entities that are out there. A billion claims and lots of existing contractors—you don't move all that quickly. Starting October 1st of this year, the existing contracting authority will sunset, and we will have to engage in any further contracting activities under the FAR Contracting Authority. The existing contractors can stay in place until we've replaced them. But any new work goes under this new authority. And we have a six-year window in which to complete that. Once we've competed these contracts, we will then, under the FAR regulations, have to re-compete them not less often than every five years. So there will be an automatic refreshing of this environment built in. And the section of the statute here requires that we consult widely about the nature of what we're up to, in particular, relative to performance requirements that we will be imposing on these contractors.

The next slide notes the Report to Congress. Mercifully, by comparison, for those of you who may have read some of our Regs, it's actually comparatively compact. I don't know how many pages it is since we didn't number them sequentially [laughter] but it is written deliberately as a report not just to Congress, but to Congressmen or women, so it is written in a fashion intelligible to people who are not deeply imbued in the archenia of Medicare. And any of you may find it interesting, because it is intended to be accessible to a wide audience. That report was issued on February 7th, and you can see at the bottom of the slide, it's in your packet, a web address where you can download a copy if you would like one. An overview of this report on the next slide, that we've got 36 million beneficiaries. We start our mission at the start. We've got 36 million beneficiaries in Fee for Service at the moment. That's the bulk of our caseload—86% or thereabout. And one of the early pages of the report shows a nice little bar graph which shows what we expect to be the enrollment in Fee for Service over the next while. And the answer is, in 2013, we expect to have about 36 million beneficiaries in Fee for

Service. That's even with the growth of Medicare Advantage Plans. So the Medicare Advantage Plans basically will take up most of the growth of the caseload in that meantime, during that period, or at least will be equivalent to that growth. But the base Fee for Service original Medicare Program will continue to be here and to be very big. And this is part of our initiative to make that program smarter. It's going to be an important part of the landscape for the rest of our professional lives, and we need to do a better job with it, and so that's kind of what we're up to here. And the other notes, I've sort of already covered about important changes to the administrative structure. There are a number of other administrative initiatives that go along with this. We are modernizing our information technology platform. We are introducing something called the High Glass, the health insurance general ledger accounting system, double entry bookkeeping making its way into the contractor environment. I hesitate to ask when double entry bookkeeping was invented, but we don't have it yet. We're not getting there. And to overcome a number of the restrictions and weaknesses in the current system, along the lines that I was describing earlier of our Title 18 Contracting Authority.

Now, the future vision on the next slide is where we're trying to move the contractors. We want to, because it's big, because it's important, we need to make this a premier health plan, if we don't think we are already. We certainly are in size. We like to say we're the largest health insurance organization in the world, and that's probably true. But we need to make sure our performance matches that size. The general picture here is the MACs, the Medicare Administrative Contractors, will serve from the provider perspective, in a single point of contact kind of role. So we're to some extent re-shifting the focuses of the contractors from being if you will, primarily claims payment enterprises to being folks who help solve problems. And they will still be heavily involved in the claim payment enterprise, but in a somewhat different way. Beneficiaries at the same time will have single point of contact. That will run through the 1-800-MEDICARE porthole, which covers beneficiary interactions, or will cover beneficiary interaction to cross the different product lines of the agency. As noted toward the bottom of the slide, we'll be leading toward a foundation for more comprehensive, perhaps more intelligent care of our beneficiaries, by integrating the claims processing of A and B in the MACs. That will not necessarily translate into the same computerized system. There are a bunch of reasons you can't go there very quickly. We've got some legacy systems here which are in need of revision and are going to be taking a while to get there, but we want to get the body of the claims within the same organization as we're moving there.

The next slide is about implementation. I'm going to come back to some other material here. It didn't quite get inserted. Implementation plan: first point is the ocean liner needs to keep steaming along. We understand the importance of cash flow. The billion claims a year constitutes something on the neighborhood of 2% of the gross domestic product. We can't afford any disruption of that. And one of our primary goals is to make sure that we move from here to there in a way that doesn't cause any disruption and is as seamless as possible. The good news attached to this is that over the last decade we have handled 15 to 20 transitions? [off mike] About 15.

Dr. Gustafson: About 15 different transitions. We've gained a fair amount of experience about how to do this. Now this will challenge us. But we're not without experience in this area. And we'll be moving toward 23 MACs as opposed to, we have something in excess of 50 contracts at the moment. I'll come back to some of the detail on this in just a moment. And there will be in addition to the primary MACs, there will be a set of what are called "functional contractors." Some of these already exist for handling things like appeals, and we will continue to have some of that workload segmented out in different places where it makes sort of from a business standpoint to do that. The next slide shows the MAC jurisdictions. Or gives the number thereof. I'll show you a slide with exactly what they are in a moment. There will be 15 of these in the new world. That will cover both A and B within the same area. They do not overlap and they segment up the country which we think is at least modestly intelligent. There will then be a cluster of specialty contractors. We, at present, have four durable medical equipment contractors, the DMERCs, we will continue to have, at least during this first cycle, the first six-year period, separate contracts to handle the DMERC business. We may revisit that decision in the second round. But at present, there seem to be a compelling set of reasons for having separate contracts for the DMERCs and we will similarly have separate contracts for home, health and hospice. Those jurisdictions will be reconfigured slightly in order to match up with the A/B jurisdictions so the DMERC jurisdictions contain the A/B jurisdictions, and there won't be any overlap there to make that all work better than it does now.

The new jurisdictions on the next slide explain how we tried to get there. We tried to achieve a reasonable balance of the number of both the beneficiaries and of providers. If you look at our current configuration of contractors, you have some that are really quite teeny and some that are quite big. And we've leveled up in this area, so that the new areas will be roughly within spitting distance of the size of the large existing contractors. So we've already, if you will, got proof of concept here. We've shown somebody can

handle the business of this order of magnitude and we now want to achieve the economies of scale that are attached to that across the country. So I said it all even better than the slide did.

The next slide shows you the jurisdictions that we have proposed. This, just to, I think there may be a slide further on that tells you the state of play here, but we have issued in the Report to Congress, the jurisdictions are not laid out there, but we have issued this material in connection with what's called a Request for Information relative to the two different species of contractors that are coming up first. We're expecting, the pattern by which we're expecting to proceed. This is called a 2-round model. But we kind of have a training wheels model to start it off, and these jurisdictions were chosen with a eye to market patterns, basically. So again we chose fifteen because we thought that would minimize the dangers associated with transition and balance out the achieving of economies of scale. We looked at who got care where. And the clearest example on this relates to New Jersey. Should New Jersey be grafted onto New York or onto Pennsylvania? Well, it turns out when you analyze it, folks in southern Jersey go to Philadelphia for care, and folks in northern New Jersey stay home. So they may go into the New York hospitals for tertiary care, but basically they're being taken care of at home. So it makes sense, just in order to keep stuff within the same organization, minimize disruption for providers and for beneficiaries to keep New Jersey with Pennsylvania and so that's the kind of thing we did there. We have a very heavy concentration of activity in the southeastern quadrant of the country, and so we've broken that up into a number of different entities. Out in the west, things are a little thinner on the ground, and so the areas there are larger, again by and large, the number of beneficiaries are roughly the same.

Moving to the next slide, just to show you how the DMERCs will come out, this is very close to the existing configuration of the DMERCs. There is some movement around in the Mid-Atlantic Region, I think four states will shift one way or another, but otherwise, it'll stay pretty much the same. This is the first crowd that is up for competition. They are already overdue. These are FAR contracts already and they are overdue so we're moving on those quickly. We have issued what's called this Request for Information, RFI, so the scope of work for that contract is out for comment by the contractor community. They're already and others, anyone else who's interested, the supplier community has been sending us cards and letters as well, and we expect to issue their formal document, their request for proposal at the end of this month. Award it in December, and start to move into implementation during the six months or so after that.

The next slide shows you the Home health and Hospice jurisdictions and I'm sure you will be stunned to realize this is exactly the same map you just saw, just with a different title on it. So the idea is to kind of keep the jurisdictional configuration as simple as possible. This will come at the end of the cycle. Although we have until 2011 to finish all of this work, we're actually trying to get it all done by 2009 so that we and you and beneficiaries can achieve the benefits of all of this.

The Acquisition Schedule is shown on the next slide. What's shown here is the three-cycle model. We try to portray it for optical purposes as the two cycle model. We'll do the start-up, training wheels, I described it earlier, doing the overdue DMERCs, changing them into DME MACs and that's going to be a lively competition. I believe that all of the existing DME MACs are interested in reapplying and some new guys are coming in, too. I mean this whole process has been very interesting to watch unfold because folks have been trooping in to see Herb and see Karen Jackson, who's the group director in charge of this area, and every now and then they come and see me, to say, hey, we're interested in this business. How can we get aboard? That's our major contractors have generally displayed a lot of interest, so we're expecting a fair number of our existing contractors to compete for this business. And some of them will probably win. Folks who do not now contract with us are also nipping at their heels and displaying interest. This includes for instance, some organizations that contract with Medicaid Programs in some states. I don't know if that's good news or bad from your perspective, but anyway folks who have experience in the general area, even though they have not, for various reasons, worked for us previously.

So we will do the four DMERCs and the one of the A/B areas. It will follow along after the DMERCs but in part of the first round. That's the inter-mountain West area. And then in the next two rounds, we will do seven A/Bs in each occasion and do those transitions and in that final round, we'll have not only the seven A/Bs, but also the four Home-Health and Hospice MACs.

The next slide shows you some recent activities on this line. I've sort of gone over most of this. There is sort of date strings about what we've been up to. We went out with the RFI for DMERCs at the start of February. And a day after the Report to Congress, that was kind of, the dam burst and all of the sudden we were able to talk about a bunch of things that we'd been waiting to talk about for some time. We sent out the jurisdictional maps. The we held town hall meetings, and we have sent out the RFI for this A/B MAC as well. So a matter that may be of interest to you or your associations, both of those scopes of work; the DME MAC scope of work and

the Part A/B scope of work are out for comment at the moment. Now you have to kind of love government contracting to really get into this, but nonetheless we invite your comments, or those of anyone else if you want to penetrate this stuff. Important elements of those scopes of work include how organizations are supposed to relate to providers. And there will be performance standards attached to all of that. And not all of that has been detailed yet. But we will be looking at that.

The closing comments slide here shows the website and an address by which you may send comments electronically. Section911@CMS.HHS.Gov Now, before we move on, I just wanted to mention a couple of additional points. I tried to get a couple of additional slides in here, but I don't think they made it. In conversation with Dr. Castellanos, it occurred to me that we needed to focus this discussion just a little bit more on the advantages that we see to practicing physicians coming from this environment. We're expecting that this will improve provider education and training, especially as it relates to small entities; that it will lead to simplified interface needs (we'll come to this in just a moment). Simplifying interface needs relative to claims processing. As an example, at present there are three carriers that serve different portions of New York state. In the future, there will be one MAC. There will be fewer organizations you have to enroll with, fewer organizations you have to learn disparate rules from. And fewer computer interfaces that may at present differ. So the new contractor service areas, again, will be larger. We've developed them in order to address beneficiary care patterns. If you're sitting in Philadelphia, you will need to deal with one organization for both your Pennsylvania and your New Jersey business. That kind of thing will help things out. The competition in selecting the MACs will lead them to want to provide better service to providers, most particularly, also to beneficiaries. But because we will be judging them on that, we will be judging them on coming in as competitors and we will be judging them during the course of their term, so that if they want to keep this business, they're going to have to perform well. We expect, partly because of the introduction of the High [Gloss?] system I spoke of a moment ago, to improve emphasis on financial management by the MACs by comparison to what we do today, which should mean increased focused on payment accuracy and consistency in payment decisions. So both for that reason and for the competitive pressures and for the performance appraisal, less rework, less need for you to resubmit claims, things of that sort. And you will have input. You, speaking generally will have input, in our contractor evaluation through patient satisfaction surveys. We will be conducting these independently through a

research contractor. We're piloting that activity at the moment and we'll be looking very much to see your input on that.

Another aspect I'd like to cover just briefly is local medical review policies, because I think this may be a source of interest here. We will be consolidating contractors. That will not instantly lead, necessarily, to changes in local medical review policies. That will depend partly on who gets replaced by whom where. But we do expect that there will be some streamlining of this and over time, it is likely that the MACs will introduce common local medical review policies throughout their coverage areas, throughout their jurisdictions. This is a little bit of a two-edged sword. And I believe that the Office of Financial Management has not worked out all of the details of this as yet. But just to call to your attention, it has the prospect of leading to greater consistency. Our perception is that the vast bulk of in fact local medical review policies are pretty much the same as it is. That there is not a lot of divergence from place to place. There may be on some obviously there is on some elements, and some of those may be the focus of sharp concern. The consistency that we can achieve across the geographic region may be desirable in its own light. We will also be able to have a better chance of achieving consistency between what now goes on from the FI and what goes on from the carrier. Some of the problems we have coming to us through the PRIT and through Physician Open Door forums relates to the fact that the two of them are dancing to different tunes. And this presumably will, by consolidating the A and B activity in a single entity will cause them to look at this in a more intelligent and comprehensive fashion. I believe it would be fair to say that we would try to do, any changes we make in this area would be done in as sensitive a way as we can. We don't tend to eliminate physician input. We'd continue the kinds of councils we have a present, but as I say, the details of that have yet to be worked out.

Herb's been very clear with us that we need to make sure there's some questions we can put to you. Help focus your discussion and input, and so here are a few that you may wish to chew on, although you may have other questions that you want to discuss as well. So what do you like about what's going on now? What do we want to preserve? It's not all bad. It has some good aspects to it. Insofar as we focus on improving interaction of physicians and their practices with our carriers, what do you think are the most important aspects of that? What do you want us to really zero in and focus on? And do you see other best practices around the country that we should be aware of? Maybe we are, maybe we're not. There may be reasons, we may be aware of it but can't do it yet, stuff like that. But insofar as you in the field are seeing stuff where some other insurer is doing a good

job and you'd like to call our attention to that, we'd love to know about it. So that's my spiel. Those are my questions. And I'd be happy to have any input you have today or as I said, if you want to send us comments on that address I guess you earlier, or the very back of my page is my personal email address and phone number, and happy to hear from you. Mr. Chairman?

Dr. Castellanos: Thank you, Dr. Gustafson. What I'd like to do is our role predominantly is to advise CMS on these proposed rules, and Dr. Gustafson was kind enough to ask us three questions. What I'd like to do if it's OK with other Council members if first to address each of these questions individually and then open it up to any other questions that the Council may have. First question is, again, as practicing physicians, what aspect of the existing Medicare contract operation environment do you value? Dr. Powers?

Dr. Powers: Sort of answers to, goes with one and two. But right now, in at least in my state, it's small enough that contractors [interruption] that I can call a medical director myself and I can probably get through, or else get a call back within a day or so and speak to them personally and get an answer and have a reasonable conversation. I understand in places where a couple of, they have now three states in my region to cover, that won't be quite as easy. I won't be—and then, I also value the Carrier Advisor Committee that has representation of multiple specialties and the ability for us to, on a state-by-state basis to be represented to that and get issues resolved for our own specialty if necessary, or for our own area if necessary.

Dr. Castellanos: Dr. Senagore?

Dr. Senagore: Just to follow up on that CAC issue. I think that's important, now that there will be multiple jurisdictions, rather than one jurisdiction before, you don't want to be in a position where three separate CACs came up with three separate recommendations. And that would [?] communicated between the CACs. And I think that would need to be in the program.

Dr. Gustafson: I agree. I think we need to move very carefully on those kinds of situations. And we're sensitive to that. I'm sure we will try to do something that does not arbitrarily come in and say, OK, everybody, now do it the way they do it in New Jersey, but make sure that there's consultation as we move forward. Not to pick on New Jersey in particular, you understand. [laughter]

Dr. Castellanos: Specifically, relating to this first question, are there any other comments? I would like to also mention about CACs. I think it's extremely important that we keep—I know it's unrealistic to have a CAC for each state. And I'm not even suggesting that. But I think CMS has to recognize that there are issues on

the state level that influence specifically some of the non-physician providers where the rules are different from state to state. The nurse practitioners, the physician assistants, the chiropractors, the optometrists. Each state may have similar rules, but there are differences between states, especially in the care providers, the physician assistant and what they can or cannot do. And that's going to be a difficult issue to handle, especially if the CACs represent a very large area. I can see where CAC in region where, I think it was California, to include Hawaii and California, that it's going to be very difficult to have a combined meeting. I know I talked to our carrier medical advisor. He said it was even in his region, where he is now, he even has a difficult time servicing that area himself. And now we're enlarging that area. It's going to be a challenge to put it simply.

Dr. Gustafson: I agree, although actually [Voy?] is already in California and so they must be handling it somehow at present. I don't know exactly how that's handled. But again going back to the notion that we're leveling up, but we're not going beyond the dimensions of the existing carrier base. But I appreciate the point, and I think particularly the state-by-state aspect, insofar as state law matters here, we need to be cognizant of that. We need to be sure we're telling our guys at the OFM about this.

Dr. Castellanos: I think the best aspect of the existing program is the communication that we have with our carrier medical director. At least in our area, he's easily available and we really get what we feel is good communications. The second question is: What improvement in the physicians' interaction with the Fee for Service program would you consider most important? Dr. O'Shea?

Dr. O'Shea: My question applies to this—was there going to be any need for reapplication. We've already been through one kind of hassle with getting our numbers straight. Now that we're going, I guess it sounds very good to—

Dr. Gustafson: Are you talking about for enrollment?

Dr. O'Shea: For enrollment again, no delay in payment because we have new processors; nothing like that's going to happen?

Dr. Gustafson: I promise. [laughter] There's nothing in the plan that should necessitate that. So and again, going back to one of the central points I raised about keeping the payments flowing, we don't want to be in a world where we're needing to do that. I mean the PECOS adventure has been a wild ride for all of us. We learned a lesson there. And there is a numeration problem confronting us all, that we may need to come and tell you more about it, at some later point, by 2007, the entire country needs to go to National Provider Identifiers.

That's an independent problem from this. But there's nothing in the movement from carriers to MACs that should require reenrollment and stuff like that.

Dr. Castellanos: Are there any other—Dr. Grimm?

Dr. Grimm: One concern I have about these is the communication amongst the MACs themselves, addresses this very issue that you talked about in terms of there are 15 different MACs and there are 15 different policies for the same item. And that creates a lot of problems in terms of just the efficiency of physicians or organizations in dealing—because every organization has to deal with every single MAC to discuss that issue. And I would encourage that these MACs have some mechanism with which to communicate the experience if somebody's already done it before.

Dr. Castellanos: Are there any other questions? Dr. McAneny?

Dr. McAneny: I get this sort of fits with 2 and 3 together, but one of the things that would be very helpful would be to have a prior determination of benefits. For example, the patient calls up and wants to know if I go and have procedure X or drug wire whatever, will Medicare cover this? What we get currently is you call up Medicare and say are you covering this? It's a new indication for this drug and they say, I don't know. Submit the bill and we'll see. And it would be very nice to have what other health plans will do, which is to let the patient and the doctor know ahead of time.

Dr. Castellanos: Are there any others? The question I have is one of the most important things, some things that we really find sometimes difficult is the provider-customer service centers. I assume by coning down, we're going to have more expertise and more availability for the provider-customer service centers?

Dr. Gustafson: Indeed, and we're already moving in that direction so that we have been getting, and I think Jerry Nicholson come and tell you a bit about this earlier of trying to set up within the carriers and FIs units that are dedicated to answering tough questions basically, so that we can triage, and bring if you will the tertiary cases to specialists who are more informed than the usually folks just answering the phone. So we're definitely trying to move our provider service in that direction. Not waiting for MACs, but moving now in that direction.

Dr. Rapp: Just out of curiosity, where does D.C. fit in to this map?

Dr. McAneny: You don't get paid at all. [laughter]

Dr. Rapp: It doesn't matter that much, but the reason I asked is currently the way this area is set up is the carrier covers the national capital area. And I personally think this is a good thing that you're paying

attention to jurisdictional lines because a lot of professional organizations, I know, when I practiced exclusively in Virginia, our Medicare carrier related to the D.C area, yet our state organizations, and most professional organizations have state chapters in Virginia, we had to deal, there was a line a bit south of the Beltway or whatever the line was, but most of Virginia was covered by a different carrier altogether than it is today. So when you do this, this will basically follow state jurisdictional lines, which I think is a good thing in terms of professional organizations being able to relate to these bodies. But I'm just curious where D.C. fit in there. Because it'll be different.

Dr. Gustafson: Looking at the map I would guess it's grouped in with Maryland. But I haven't heard any specific discussion of that.

Dr. Rogers: I'll have to go back and look at the list. It's too small to read.

Dr. Castellanos: Dr. McAneny?

Dr. McAneny: I have a question on the money of this. I saw that there is $56 million proposed in the budget and there's expectant savings of $900 million over as many years, but one of my concerns whenever I hear that financial incentives are going to be given to the carriers, is does this mean that if they deny more claims and therefore save Medicare money, that they will get a bonus, which means it comes out of the Physician Fee Schedule, or is this going to be new money into the program that is unrelated to denial of claims and other things, and how will you monitor to know that that is not occurring; that we're not becoming adversarial with our carriers, to say, Gee, if I deny your claim, and even though it sounded reasonable, then, my carrier looks better. We're going to make more money.

Dr. Gustafson: I understand and appreciate your concern and let me assure you that we would not look to the carriers to deny claims as a means of saving money. That's not what their in the business of. In the first place, that's not what our mission is. But I appreciate your concern. Let me lay out just a very brief compass, sort of the financial picture here. The $56 million that you mentioned is an investment amount. In order to make this transition, we will have a lot of expenses, both in terms of just reshuffling stuff, redoing the information, technology platforms and so forth. And also we will need to pay transition costs, termination costs to our existing contractors, who are paid, basically, on a cost basis. So there will be several years where the program will need to invest in gross terms. We're expecting to have reduced administrative costs for ourselves. We're expecting to see reduced costs for providers, and we're expecting to see reduced beneficiary costs as a result of

those investments. So there will be a break even point a few years out, and we're going to need to work with the appropriators in dealing with all of this. The reduced costs to the program and service dollars come largely from more appropriate payment. So there may indeed be some denial of claims associated with that, but presumably, it would be for denial of claims where we can now see the interaction of A and B in a more clear fashion so that we can understand the medical necessity more clearly and things of that sort. We expect to see administrative savings to the program because of competition improving the interest of organizations in being more fit fiscally and otherwise. We will expect to see some affects of consolidation, because we will be able to achieve greater economies of scale. We have some very small contractors at the moment, and technology drives us in the direction of larger entities. We expect to see some effects because of incentives that we will be providing to the contractors and because we will be contracting in this FAR environment in a way that will focus on outcomes as opposed to process requirements. So all of those can lead to improved administrative efficiencies. We also expect to see some affect on the bottom line of physicians. It may not be large. But the sort of things I was talking about earlier of essentially reduced hassle and interacting with us, fewer entities you have to interact with, improved sort of front end capability of things of that sort. So we look for potential administrative savings in over $100 million from that, and that's a number which requires a lot of assumptions behind it, so we have not been broadcasting it widely. But we think those savings could be real.

Mr. Kuhn: Let me just tag onto that for a quick moment. A couple of additional observations here. One is one of the things is when our Office of the Actuary looked at this, they really saw the opportunity for better provider education, so the quality of the claims coming in. Gus talked a little bit about the interaction of A and B, which is key, but this consolidation, better provider education, better interaction between both the payer, us, and our contractor and the provider gives better claims coming in, so a lot of these redo problems are not there, as well as inappropriate claims coming in. And I think that's a good thing. The other issue here is that as we really move to new technology, one of the things that hopefully will save you all on your bottom line, is the fact that we need to be better in terms of how we interact with you, and there needs to be better customer service with these folks. And a lot of that is web enabled. I mean, the fact that you know, you talked earlier about this notion of kind of a prior determination of benefits. That might ultimately be an opportunity that we can look at there. But importantly, the fact that you have back office staff that are calling carriers daily, trying to find out about patient eligibility, claims status, remittance advice, all of this stuff that should be web enabled now, and it's not.

We're moving pretty resolutely with some of the carriers to move in this direction but those are huge savings, that could harvest and accrue to you all in that regard, because too many times I've talked to physicians, who say their staff called in the morning, and they get one answer. And they call in the afternoon on the same patient and they get a completely separate answer. This needs to change. We need to be better business partners there. And I think this is going to be a huge improvement in this, in this reform.

Dr. Castellanos: Dr. Urata?

Dr. Urata: One comment on something separate from the three questions. If that's all right. The comment is when I talk to my administrator regarding electronic billing and that interaction, we like that. It's really improved things once we got over the HIPAA problem, because the person we worked with wasn't HIPAA compliant for a long time. Took him a long time to become HIPAA compliant. So I'd like to go on to a question separate from those three questions that you asked, and that is, you have separate jurisdictions for DME, A and B, and Hospice and Home Health Care. So if there are three different companies that deal with this, or win the contracts, my patient that has a stroke is in the hospital, we're dealing with one company for A and B, I want to send them home with walkers, so they have to deal with another company for DME and then I send them with Home Care, to do physical therapy at home and so then they have a third. Is that going to be a problem? Or why is there not going to be just one company dealing with all three of those things? Because the patient ends up seeing three companies, three different bills. One company might deny them the walker and Home Health would be acceptable on a first A and B, of course it would be acceptable. But my patient's going to end up with three different people to deal with, and it seems to me to be even more efficient if you had one company dealing with the whole patient, and we didn't do that.

Dr. Gustafson: Yes, let me go into this just for a moment because it is a little bit subtle. The good news is even the description you described is worse today. So we'll be in better shape. All you have to do is add a hospital scenario and you've got at least one other entity in the mix.

Dr. Urata: Yes, now we're dealing with four. Now we got it to three. One is better.

Dr. Gustafson: One may be a goal we are able to achieve in the next decade, but was not one for a variety of reasons, including some important technical reasons we were able to achieve right away. Just to give you one insight on the durable medical equipment, for instance, they use a completely separate claims processing system from either A or B. That means that you can't move them to a new platform right away because you have

an overlap problem. So that given we had to move on them soon, we needed to keep them separate. The Home Health is a similar type of store. What we may anticipate is a later point in which we knit all this back together. That would be what we call a second round, kind of concern. And we agreed that the consolidated information about an individual patient that consolidated interaction with a single entity would be desirable. You recall how I described the A/B MAC as a primary point of contact. So the way we are envisioning this is those guys are not only the people who are in charge of seeing that the claims are processed properly for A and B, but they're also the problem solvers for the other specialty and functional contractors, that you are the beneficiary, and may need to interact with. So this may not mean that you would submit your claim for DME to that A/B entity, but in so far as they're a problem, they're in the loop, helping to solve it across all of these concerns. So that's the face of Medicare, if this isn't the wrong image, on the ground, in the community, the folks who are out there making sure that all of this is working right. To give one additional point on this, the claims processing we're expecting to consolidate in what are called enterprise data centers, so that these claims will still, if you will, be owned by the A/B MACs, but the actual back office processing will happen in entities that are basically computer centers. Some of that happens at present. It doesn't need to be associated with the A/B activity as we envision it. And so that's why I say there will be some refocusing of the activity of the contractors in that direction.

Dr. Castellanos: Before we open up, are there any other comments on his third question? Best practices that we see from other insurance companies that we may want to suggest to them? Dr. Johnson.

Dr. Johnson: Well, to applaud all your work, the comments you were just talking about on the web enabling. I think that that will certainly help, especially when you get into the smaller practices where you've got staff that is cross-trained and that you may have limited time frame to be tied up on the telephone, where you can do a lot of things web enabled. And that certainly would be extremely important. One of the things, when we talked with our carriers has saying, well, you're getting into certain privacy issues on the web, and the HIPAA and what have you. But those are things that some of the other carriers that we're dealing with the office that helps to decrease some of the front end and the rear end hassle factor. And keeping staff so tied up when you need them in other areas doing other things, that that's huge. And I think that would make a big impact to the provider community. It serves the bennies well, and it's going to decrease administrative costs. It's a win. So as soon as you can get more toward that web-enabled, it's going to be a lot better.

Dr. Castellanos: Any other points on his third question? Let's just open it up, any other questions?

Dr. McAneny: I like the idea a lot of having the Part A and Part B being consolidated into one area. I'm wonder if this is the start of a breakdown of all of the current legislative and administrative rules that make it so that it's impossible to have the money follow the service. And where I'm going with that is that as more and more physicians' services and operative services and everything else are taken out of the hospital and into the office setting that just increases volume intensity for our part of Part B, but it doesn't seem to ever affect Part A in terms of knowing how much less money is being spent in that system. So I'm hoping that you're going to tell me that this is a start to be able to have the actual payment dollars follow the procedure to whatever setting it's given.

Dr. Gustafson: I think you're going a bit beyond what we're up to with Medicare contracting reform, but let me suggest that precisely the integration of A and B administrative functions is an enabler. It could enable the sort of policy change that you've just described. That would require some significant reworking of our statutes in order to be able to do that, but it makes it a lot better if we have A and B in the same place. The same is true on projects such as the Coordinated Care Improvement Program, Chronic Care Improvement Programs, CCIP, where we are trying to have providers, or have providers and their helpers look at the total care of patients that are particularly difficult. If you have an information environment in which A and B are in the same place, you're going to facilitate our ability to do that, even if you haven't yet integrated the claims streams, which are in a place where you can for instance, provide incentives to these organizations to pay attention to the interaction of A and B. So it becomes partly their problem and not just your problem or our problem. We regard this as sort of a generational point. In the sense that this is our choice for a generation is to bring these together. Now's the time to do it and we want to go that way and we'll see where the future carries us.

Mr. Kuhn: One additional observation about that. To a degree part of your question deals with the question of site-neutral payments, regardless of what the service is inside, it ought to be neutral. Just maybe for your reference later this week, the Medicare Payment Advisory Commission MedPac is meeting later this week, and as I look at their agenda, I think the first day they are going to begin some of these general discussions in these area so that might be good information to look at for MedPac later this week.

Dr. Castellanos: Are there any other questions? What we'd like to do after each discussion, instead of waiting til the end of the day is to make any recommendations that you may have at this time, pertinent to contractor reform. Do we have any recommendations? Dr. McAneny?

Dr. McAneny: Yes, I do, actually. First of all, I'd like to have PPAC recommend that any money for incentives to the MACs be new money, or come out of administrative savings, and not come out of the Physician Fee Schedule. Just to put it in writing.

Dr. Gustafson: We certainly welcome the recommendation but in fact, the way our budgeting works, that would be an automatic consequence. The incentive payments have to come out of our administrative stream and not out of benefit dollars.

Dr. Castellanos: Do you want to read that back to us?

Ms. Trevas: PPAC recommends that any money for incentives to MACs derived from new funds for administrative savings and not from the Physician Fee Schedule?

Dr. Castellanos: Is that?

Dr. Powers: Say it again?

Ms. Trevas: PPAC recommends that any money for incentives to MACs derived from new funds or administrative savings and not from the Physician Fee Schedule.

Dr. McAneny: Not from refunds, I didn't say that.

Ms. Trevas: Refunds?

Dr. McAneny: Being new money, new funds.

Ms. Trevas: That's what I said. Derived from new funds.

Dr. Castellanos: Any additions to that, call the question. All in favor? [Ays] Opposed? Are there any other recommendations? Dr. Powers.

Dr. Powers: Actually I have. First, PPAC recommends that CMS continue the CAC program, the Carrier Advisory Committee program.

Dr. Castellanos: Are there any other comments on that? Could you read that back, please?

Ms. Trevas: PPAC recommends that CMS continue the Carrier Advisory Committee program.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed. You said you had a second one?

Dr. Powers: PPAC recommends that CMS keep the Carrier Medical Directors' office accessible, even if that means adding staff positions.

Dr. Castellanos: Are there any additional comments on that? Could you read that back, please?

Ms. Trevas: PPAC recommends that CMS keep the Carrier Medical Directors' offices accessible to providers, even if that requires the addition of staff positions.

Dr. Castellanos: I'll call question on that. All in favor? [Ays] Opposed? Are there any other recommendations? Dr. McAneny?

Dr. McAneny: PPAC recommends that as part of the contracting reform, that more integration between parts A and B be developed, even if new legislation is required, including having the money follow the service from Part A to Part B.

Dr. Castellanos: Are there any questions on that? Any additions? Could you read that back, please?

Ms. Trevas: PPAC recommends to CMS that as part of contract reform, CMS institute more integration of parts A and B, even if new legislation is required to allow funds to follow services.

Dr. McAneny: From Part A to Part B.

Ms. Trevas: From Part A to Part B.

Dr. Castellanos: From Part A to Part B. I'll call question. All in favor? [Ays] Opposed? Are there any other? Dr. Urata?

Dr. Urata: PPAC recommends that CMS look into incorporating Home Health, DME and A and B in [off mike] jurisdictions.

Dr. Castellanos: Are there any other comments on that? Could you read that back, please?

Ms. Trevas: PPAC recommends that CMS look into incorporating parts A and B, Home Health and Hospice, and DME into a single jurisdiction in the future.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? Are there any other? Dr. Johnson?

Dr. Johnson: PPAC recommends that movement toward web-enabled access to enhance quality of care and reduce the front end and rear end hassle factor.

Mr. Kuhn: How about web-enabled access to improve provider base service?

Dr. Johnson: Yes.

Mr. Kuhn: Maybe that might be a way to capture that. To improve provider based service.

Dr. Castellanos: Could you rephrase that to include the web?

Dr. Johnson: PPAC recommends movements towards web in access for provider-based service to improve quality and reduce the front end and rear end hassle factors.

Dr. Castellanos: Are there any questions on that? Would you please read that back?

Ms. Trevas: PPAC recommends that CMS move toward more web-enabled access for provider-based services to improve the front end and rear end hassle factors.

Dr. Castellanos: Get a little anatomic, I guess. [laughter] That's good. I'll call the question. All in favor? [Ays] Opposed. Are there any other recommendations by PPAC at this time? Seeing none, I guess Dr. Gustafson—

Mr. Kuhn: He had to run off.

Dr. Castellanos: Well, please let him know that we certainly appreciate his presentation. There's a lot of interest in a lot of good direction that we see going and we congratulate he and CMS in the direction you're going.

Mr. Kuhn: Thanks for your comments on this one. This one's pretty important. We want to stay close in touch with you on a before basis on this one, because there's a lot of changes here, but there's so many opportunities for higher quality, better service here that we really want to stay engaged with you on this one.

Competitive Bidding on Drugs

Dr. Castellanos: Staying on schedule, the next talk is Competitive Bidding on Drugs. This will be presented by Mr. Donald Thompson, Director, Division of Outpatient Services, Center for Medicare Management. He'll address the Competitive Bidding on Drugs. It's good to see you again, Mr. Thompson.

Mr. Thompson: My pleasure. Today's topic is the Medicare Part B Drug Competitive Acquisition Program. We have published a Proposed Rule on this area. This is §303 D of the Medicare Modernization Act. That went on display February 25. We'll have a 60-day comment period. And the comment period will close on April 25th. We expect a great deal of input, interest from physicians, central drug suppliers, beneficiaries, other payers, as well as drug manufacturers. There are a number of different areas of the Proposed Rule, so one of the, two of the largest being what drug categories should be included in Medicare Part B Drug Competitive Bidding, and what geographic areas that we should include in the program. Again, this is for Medicare Part B drugs, so in general the Medicare Part B drugs are the physician injectible drugs. They are not usually self-administered. Drugs furnished through DME, and then there are some specifically statutorily covered drugs, like oral and dymedics, oral immuno suppressives and oral anti-cancers. So in that kind of universe, the question becomes what drugs should be included in the Medicare Part B Drug Acquisition Program. We are proposing to look at

physician administered drugs, so although we are seeking comment, we are not specifically looking at DME furnished drugs, or some of the other oral drugs that are provided under Medicare Part B. So that's probably the first major point. But again, we are seeking comment on the whole universe of Medicare Part B drugs, but when we looked at the statute, the statute does discuss in some detail, the physician involvement in this process. And it does at least appear to us, to envision a system that is geared towards the physician injectible drugs, at least initially. At least would be required to include those.

Within that, we're looking at drugs commonly furnished by physician specialties is how we discussed this in the Propose Rule. So the concept being we would want a physician to be able to opt out of the drug purchasing business or at least for the vast majority of cases, be able to opt out of the drug purchasing business for Medicare beneficiaries. So what we would be looking at is for the vendors to be required to furnish all the drugs that that physician specialty would commonly furnish. So that would be the category. So for example, for oncology, the category would be all the drugs commonly furnished by oncologists. For urology, all the drugs commonly furnished by urologists. And that's kind of the framework around which we're seeking comment here. We're not limiting it to that, we're just saying here's for point of discussion, and getting some input and seeing what physicians think and what some of the vendors think and other members of the public about that as kind of a basis for discussing the physician-administered drug categories. So one of the questions for the Council, and we can kind of discuss this at the end, would be kind of what drugs should be included in the program? And is this an appropriate framework to think about kind of all the drugs commonly furnished by a physician specialty and what specialties should we include in 2006. The Secretary has phase-in authority for this program, so we'd be seeking input if the Council would determine that that might be an appropriate approach about what physician specialties to be included in 2006.

Next question would be potential geographic areas. Again, the Secretary has discretion in determining what geographic areas, what the geographic areas should look like for the Medicare Part B Drug Acquisition Program and also authority to kind of phase those areas in. In the Proposed Rule, we discuss the program being nationwide. We discuss potentially a regional framework. And we also discuss a statewide framework. We do not propose going below a statewide level. Obviously we're seeking comment on the issue. We think that based on request for information that we put out back in December and the responses we got from that from potential vendors, it would appear that the vendors do not necessarily operate on a sub-state basis, so on a basis of that

information, we said somewhere between statewide and national or regional, seeking comment on the regional and national and the statewide, not delineating in the rule, not naming specific states, but again looking for input from the public on what those areas should be. And again, the phase-in. So the question for the Council would be what framework, for the geographic areas, national, regional, statewide? If you think that's appropriate, and how we would phase that in.

Then also discuss how the competitive bidding process itself would work. We are proposing a vendor who wishes to participate in the program would submit a bid to Medicare for supplying drugs. A vendor would have to first demonstrate that it met rigorous standards that we set out in the Proposed Rule for quality, program integrity, financial stability and service. For vendors that meet those standards, we would then select the winning vendors based on the bid price. Some of the standards that we talk about in the rule and some of these are statutory and some are regulatory, is that the vendor would be required to acquire the drugs directly from the manufacturer, or from the entity that acquired the drugs directly from the manufacturer. The vendor would be required to be licensed to distribute drugs in every state in which they are bidding. The vendor would have to have the capacity to ship five days per week in an emergency situation. The vendor would have to supply audited financial statements to us, and the vendor would have to have at least three years' experience distributing Medicare Part B drugs.

We are proposing to select up to five winning bidders in each drug categories. So for vendors that meet all the standards, we would then take the top five based on their bid prices. We are also proposing that we exclude any vendor with prices higher than 106% of the weighted average sales price of drugs in that category. You may recall currently in 2005, Medicare Program is paying 106% of the average sales price when physicians buy and bill the drugs. Under the current system, the physicians buy the drugs, bill the program, and we are reimbursing at 106% of the average sales price. And that is based on data that manufacturers submit to us quarterly.

In terms of the claims processing framework, we would envision no change for the physicians in terms of whom they send their claims to. So physicians would bill for drug administration, and those would continue to go to the local carrier. The vendor would submit the claim for the drug. The physician under this program, remember, this is a hybrid program, so physicians have the choice of continuing to buy and bill drugs at ASP plus 6 and billing as they always have, or choosing to participate in the drug competitive acquisition program in

which case they no longer purchase the drug. They get it from the vendor, and they also no longer bill for the drug. The vendor would bill for the drug. So the vender would send the claim for their drug to a designated carrier. We discussed having a single designated carrier, that would process all the drug claims, while the physician administration claims would continue to go to a local carrier.

One of the issues that we discuss in the Proposed Rule has to do with the verification of drug administration. The statute requires that both the beneficiary cannot be billed until the drug is administered, and vendor is responsible for billing the beneficiary for co-insurance and any applicable deductible. And also, we cannot pay the vendor. The vendor payment is contingent upon the drug administration. So we need a mechanism to verify that the drug was actually administered. What we discuss in the Proposed Rule is a tracking number system. This had been proposed to us. There were some vendors as you know, we look at their requests for information, [?] drug vendors gave us information under that. We also had an open door forum, where we took comments from the public on §303 D, the Competitive Acquisition Program and as a result of those, we discuss in the Rule, a tracking number system where the vendor, at the time they ship the drugs, would attach a tracking number to the shipment, to each of the drugs in the shipment, and the physician would then put that tracking number on the claim when they submit it for drug administration. In that way, we'd be able to automate the verification of the drug administration in our claims processing system. So the vendor would submit the drug claim with the tracking number on it. The physician would submit the claim with the same tracking number on it. We'd be able to marry those up in our claims processing system, and then enable payment to be made to the vendor and then co-insurance and the deductible to be billed to the beneficiary.

I wanted to leave a lot of time here for discussion. I know this, we discuss this at least in concept on a number of occasions prior to this, but now that the Proposed Rule is out, and we've put a little more flesh on some of the ideas that we've discussed prior, I wanted to give the Council an opportunity both to ask questions about the program and I hopefully can answer in a little more specificity than I have prior to this. But again, we are in a comment period, so I will say that I would not be in a position to prejudge any of the comments that might want to come in. We're obviously going to have to weigh all of the comments that come in from all the interested parties. So I am somewhat restricted in being able to respond back, but definitely am seeking input. We are all seeking input on kind of the aspects of the program that I just described, so some of the specific questions for the Council; what drugs should be included in 2006? What areas should be included in 2006? And

the framework for both of those? What quality criteria do physicians use now when selecting a drug supplier. Obviously a key component of this is that we want quality vendors in the program, quality drug suppliers, and so I would ask the Council to address for the physician specialties that supply drugs? What criteria do you use now in your practices to insure that you are working with a quality drug vendor, and then also comments on the drug tracking system. Obviously there are some who have commented that physicians should just bill the drug administration. The vendor should just be able to bill for the drug claim and both would get paid. However, we do have this statutory requirement in terms of the verification. We are trying to design a verification system that has the least administrative burden possible, as far as administrative resources. We're proposing the tracking number system, but are seeking comments both on that system or on other ideas for how we might be able to verify drug administration payments. So those are kind of the four. What drugs should be included, what areas, what are the quality criteria that you currently employ, and comments on the drug tracking number system. And of course we want to answer any questions you have about the program. Sitting to my left—I apologize for failing to introduce at the beginning as I dove right in, is Cassandra Black, who has been one of the key analysts who've been working on this program. And in no small part, it is a tribute to her and the rest of the staff that we were able to put this Proposed Rule out on February 25th.

Dr. Castellanos: Mr. Thompson and Ms. Black, we certainly appreciate the presentation. And you're right, this is very informative, but I'm sure it asks a lot more questions than—there could be a lot more questions asked. Again, in the same realm, we'd like to try to answer his questions, or CMS's questions. We may answer them by asking questions, too. Are there any questions? Dr. Powers?

Dr. Powers: Just to answer one of their questions. We don't have that many drugs, but for instance, Botox, we usually get from the company that makes [off mike] company. And since we don't have that many drugs to deal with, it's easier for us to do that than to go through a clearinghouse. And to answer another question, as far as a list of drugs is concerned, it might be easier if we emailed that to you or from the specialty society after we gather that from all our different subsections. And my next question is, how soon, I hate to use the case of [Tysobery] because it was yanked from the market as soon as it came out, but how soon would new drugs be available to us once they were FDA approved and manufacturers had them.

Mr. Thompson: As part of the contract for new drugs, that would be furnished by that physicians specialty. The vendor would be required to supply those drugs. Obviously because the bidding process would

have closed at that point, they will be reimbursed—or we are proposing that they would be reimbursed at ASP plus 6, the same as we would pay in the physician office for those new drugs.

Dr. Castellanos: Dr. Urata?

Dr. Urata: I just have an answer to your question on geography. I would recommend regions, because some states are so small for economy of scale, I would go regional. And you might even consider those 15 A/B regions. Because that was based on economy of scale as well, so maybe the same thing would compare with drug purchasing.

Dr. Castellanos: Dr. McAneny?

Dr. McAneny: I hardly know where to start! [laughter] I'll start with trying to answer some of your questions; which drugs you want. If you're going to do it as oncology, then obviously we want all of them because any one you eliminate, the next patient I see will need that specific drug. And the second thing is that we don't just give chemotherapy in the office for example. We're very much below water right now on ASP plus 6 for Ceftriaxone, which we use a lot as a daily IV antibiotic because I can keep people who are neutropenic-septic but still have blood pressure out of the hospital if I can treat this in the office. But so I would love to be able to have your CAP company eat the loss of Ceftriaxone and have those antibiotics provided by someone other than me. Because we are so far underwater for doing that. Obviously, the easy way to do now is all neutropenic-septic patients go to the hospital and you can pay for them under Part A instead of us trying to do that as an outpatient anymore. The criteria that we use to select a vendor to provide the drugs: first of all I want to know that I have a good chain of control. I want to know that this vendor is going to get it from the manufacturer, that they're going to handle it properly—it's not going to bake on a loading dock someplace—and it's going to be brought to my office in pristine condition. Secondly, I noticed in the Proposed Rulemaking that you're not offering any administrative costs—

Mr. Thompson: Just a—I have a question. How do you verify a good chain of control? What does your office do to verify that you have good chain of control?

Dr. McAneny: When we look at each individual group that we purchase drugs from, and we know what time it left the manufacturer, and we know what time it arrives at our office, and we know the shipping mechanisms. So if it's delayed, we just don't accept that drug.

Mr. Thompson: You would request that we have some mechanism, or the vendor has some mechanism for supplying that kind of level of detail as well, kind of what the drug pedigree was.

Dr. McAneny: If I'm going to put a drug into a patient's body, I want to know that that drug is in the exact condition that it needs to be for patient safety reasons, yes.

I noticed that in the Proposed Rulemaking that you don't even offer the CAPs any money for wastage and shrinkage. And I don't know of any industry that does not have that in its inventory management. There are going to be bottles that get dropped, or they're going to sit in the sun on a loading dock someplace, or they're going to have something happen. And so I think that's a significant oversight on whoever does it. You have to have that in or they'll lose their ASP plus 6 on just loss in the inventory.

Mr. Thompson: On that one, unfortunately that's a statutory—

Dr. McAneny: You can't do it?

Mr. Thompson: You can't do it. The statute explicitly says that the vendor cannot include the cost of wastage in the [?].

Dr. McAneny: OK. The next thing I look for in the quality criteria is whether or not they're going to do replacement drug if, basically replacement drug for free when we drop the vial, or we say the vial is cloudy when it arrived and I'm not going to use this vial and you've sent it to me. If I have to send it back, I want to make sure that I'm not having to pay the freight out of my E&M-codes to ship this drug back to the manufacturer to prove that it was truly a cloudy bottle or that it looked like it was contaminated, or that the seal was broken or that something else was wrong with it and I wasn't willing to administer it.

When I look at a drug vendor, the other thing that I want to know is what do they do about my uninsured patients and what do they do about my patients who don't have Medigaps, or any mechanism to make that 20% co-pay. And so when I purchase drugs from a manufacturer, I want that manufacturer to show up in my office with free drugs for folks who have no bucks. And I don't see any way that this system is going to allow to have that happen. So that the patients now who don't have the 20% for their chemotherapy—are they going to just get denied? Physicians, being not very good business people, have always just sort of eaten that amount of money, but now without the margin we can't do it, and somehow I have a difficult time imagining a large multi-state corporation deciding that it's going to be nice to Joe Sanchez from Albuquerque, South Valley. And the other thing that I want to know is that they're going to make it as easy as possible for me for tracking these drugs

because the idea of having a tracking number on them and having to submit that number and make sure that the right bottle goes to Mrs. Jones and not to Mr. Smith sounds to me like an administrative nightmare. And I don't see any place in the fee schedule where administrative fees are going to be covered on my end of it.

Mr. Thompson: And on that one, just to clarify. We weren't talking about a separate physical inventory. So you would need to keep a tracking number. The drugs themselves could be combing physically, but you would just need to keep track of the tracking numbers associated with that beneficiary and do the drug administration. Just to clarify that. I'm not saying that that necessarily eliminates the problem. But it is not a physical, necessarily separate refrigerator for each beneficiary.

Dr. McAneny: Yes, I do understand.

Dr. Castellanos: Are there any other questions? Dr. Hamilton?

Dr. Hamilton: Would there be a distinction between drugs that would be used for therapeutic versus diagnostic purposes? Some drugs are used for both, especially in endocrinology.

Mr. Thompson: In what we're proposing, it would be all the drugs commonly used by that specialty, so it would be whether for diagnostic or therapeutic purposes.

Dr. Hamilton: As long as there was a code for the—

Mr. Thompson: Right, with respect to the vendor. Yes.

Dr. Castellanos: I'd like to ask a question concerning the vendors. The issue the FDA is really struggling with now is counterfeit drugs. We've seen it in oncology in Kansas City, we just saw the 3rd largest drug chain in the United States, Rite Aid bought millions of dollars of counterfeit Lipitor. And they have the ability to absolutely look a lot closer than I do. That's a very small corporation. What assurity do we have from the vendors? Because there was nothing in your presentation that the vendor is going to give us the medicine that they bought from the manufacturer. Right now, when we buy it from the manufacturer, we have some assurity of the quality and that what we're buying. But when we buy it from a third person or wholesaler or a vendor, there's no assurity of that. What assurity are we going to have that we're giving that drug and it's not a counterfeit drug?

Mr. Thompson: I think that this is to a certain extent, a subset as you mentioned, of a larger issue in the country of how to deal with counterfeit drugs. With respect to this program, there is the statutory requirement that the vendor has to get the drug directly from the manufacturer or from someone who got it directly from the

manufacturer. And they need to be able to demonstrate that to CMS that that is in fact how their relationships work when they give us the bid prices. In terms of what would happen with respect to any new FDA initiatives, we require the vendors to comply both at the time that they're bidding and throughout the course of the contract with any applicable state laws or FDA regulations with respect to drug distribution. So there's no lesser standard in place for the vendors than there are for other drug suppliers in the country and as systems evolve for handling counterfeit drugs, those are automatically incorporated under the terms of the contract into the requirements for the vendors.

Dr. Castellanos: Dr. O'Shea?

Dr. O'Shea: I want to first address what I think is a basic premise that we haven't opened up yet. I believe that CMS should use its administrative authority to remove Medicare coverage to administer drugs and biologics from the physician payment formula, retroactive to 1996. What's going on here. My bottom line is that we are being punished for having advances that pharmaceutical companies have brought to us and so are our patients. IV-administered drugs are just that. They are IV-administered. When I write a script, it's the same thing as giving a drug to a patient. When I have to treat a more advanced disease, I shouldn't be actually punished for that. There are ways to treat cancers that actually are with oral medicines, Ketoconasol and Prednisone have become another avenue to treat prostate cancer. But why should a patient have to use those, and that's what we're going to kind of come down to if it keeps on. What we're saying is again it's a limiting patient access to care when we limit the type of care that we can give. And I'll just open that up. I think that that has to be addressed because we're kind of putting all the dressings on a window that's broken.

Mr. Thompson: Sure. And I think in terms of inclusion of the drugs in the SER with respect to the Competitive Acquisition Program, there is, we did not propose kind of a separate treatment for drugs under the Competitive Acquisition Program for those drug expenditures versus drug expenditures in the physician office. So there's nothing on that particular issue, there's nothing in the CAP program that would differentiate our handling of that from how we would do it in the physician office. Obviously the issue of the SGR and the payment updates and the SGR definition is being actively discussed in a variety of forums not just this one. And I understand your comment. We can take it as input. But just wanted to clarify that there's nothing particular in the drug acquisition program that addresses that differentially than it does the larger issue.

Dr. Castellanos: Dr. Rapp?

Dr. Rapp: Just out of curiosity how did you arrive at the decision to group the drugs according to specialty? I'm not involved in this, but Dr. McAneny mentioned Ceftriaxone. That's obviously not a drug that unique to oncology or probably any other field, but I would envision one group of drugs—you're going to have that same drug in how many ever specialties you come up with. And it would seem like the real issue is who's going to give you the best price? And who can deliver the drugs without regard to—I mean why is that of significance to you to group them by specialty?

Mr. Thompson: I think there are other ways that you can cut the categories, but the driving principle here was giving the physician the ability to opt out of purchasing drugs for Medicare beneficiaries should they choose to do so. So we really wanted to be in a situation where if a physician said for my Medicare beneficiaries, you know, I don't want to be in the buy and bill program anymore. I don't want to be doing this. I just want to get the drugs from the vendor. I don't want to have to worry about purchasing them myself and billing for it. We wanted to give the physician that out. And if you cut the category smaller than that, like say you took the top three oncology drugs just off the top of my head, then for the rest of the drugs, the physician, the oncologist in this particular situation would be forced to continue to buy and bill those drugs. And that was not a place where we've, at least in this Proposed Rule, necessarily wanted to be. We wanted to give the physician the opt out. So the way we felt was the best way to do that was to say, OK, this is the category. This block of drugs. And that's what you, the physician can choose, and that's what the vendor has to supply.

Dr. Rapp: Did you consider for example just grouping them according to the frequency with which they're utilized? In other words, you've got a whole list of probably form payment data, which medications are actually administered in a physician's office and which ones are the most common, and try to cover 70, whatever level you felt you could handle initially, 75%, 90th percentile, 99th percentile of drugs administered.

Mr. Thompson: Absolutely, and that would be a very good comment on the rule and that's the type of information we're looking for. If people feel, I guess there's some advantages to maybe doing drugs commonly furnished by a physician specialty, but in fact for reasons X, Y, and Z by maybe just doing 75% of utilization, 80%, 90%, that's a comment that we would definitely weigh and give consideration to in the Final Rule.

Dr. Castellanos: Dr. Senagore?

Dr. Senagore: I would just follow up with that that it may be good to cut it by drug class, so that if you wanted to participate in chemotherapy drugs, but said [?] antibiotics because I don't use them now, or

alternatively you would buy both of those classes, you should have the ability to opt out by class rather than simply by volume.

Dr. Castellanos: In that same realm, even within the urology community, some doctors give systemic chemotherapy, some don't. I think there's going to be a significant variation within specialties outside of oncology what is or is not given. So it's going to be difficult to make it specific to specialties. Are there any other? Dr. Hamilton?

Dr. Hamilton: What is the window for specialty societies comment on this?

Mr. Thompson: April 25th is the closing period.

Dr. Castellanos: Dr. McAneny?

Dr. McAneny: I'm just curious as to how you intend to have the CAPs pay for off-label use of drugs. My concern is that the label indications, being an expensive thing for a drug company to develop are often not the same as the number of indications that is supported by evidence-based medicine. And so frequently, when we are using a drug for a particular type of cancer, it's not a label indication. Yet, most payers, including Medicare, have already paid for this. But often that requires the process of shipping articles to the carrier medical director etc. to get that included as an indication, or going to the local CAC and explaining why we're using it. I have difficulty envisioning this corporation being very interested in delaying their cash flow to wait for the CAC process to work, or to try to go through the appeals process. So I'm curious as to how you would envision that occurring for off-label use.

Mr. Thompson: The CAP program does not change any aspect of the current system for drug coverage. So all the current mechanisms that we have in place, whether it be an NCD or a local determination, continue to remain in place. So it does not impact that process at all. With respect to whether or not the CAP vendor is required to supply the drug or not supply the drug, there will be a set category, with the exception of new drugs that might come along, of drugs that we would include in the category that the vendor would have to provide. So if that answers your question, if the drug is in there, the vendor has to supply it, whether it for an on-label or an off-label use. To the extent—that's the vendor getting the order and having to supply it. Now the question would then be just the normal coverage process that we have, whether that be a local coverage determination or NCDs, is the drug covered for that particular use and that's a kind of a separate distinct issue. But nothing in the CAP program in any way modifies the existing coverage process.

Dr. McAneny: Occasionally, when we're giving an off-label use, it gets denied. And we end up as physician practices, eating the cost of that drug. Who will be responsible for eating the cost of that drug if it's denied?

Mr. Thompson: If it is denied for medical necessity, the vendor will not be paid for it. We only pay for services that are medically, reasonably necessary. So the drug was provided that wasn't medically reasonably necessary, there will be no payment to the vendor.

Dr. Rapp: Upon that, though, can the vendor get the money from somebody else? Is there any provision in the program that prevents them from billing the patient, or billing the doctor?

Mr. Thompson: It's the same criteria that would have applied under the physician, so no change. The vendors are required to work under all the same rules that a physician practice would be.

Dr. Castellanos: Dr. Grimm?

Dr. Grimm: This is a just a point of edification for me in terms of how this works, because I never dealt with, or my practice never deals with vendors separate from the manufacturers. We've always dealt directly with manufacturer for drugs that we need, so now we're putting another person between us and that manufacturer. To me, if I'm in a business, my lab, more cost. OK, so that's an issue that I have. And the other issue is a curious rule here, it says that I don't know how many are out there. And I'd like to know how many are out there. And then you have a rule here that says that you can't even participate unless you have three years experience. Well doesn't that exclude just about everybody who wants to get into this business except for exclusive few that may have been already doing it? And then give them, no one else can ever enter. Because how are you going to get three years of experience in this business, without being able to build it? Where are you going to get it? If you don't allow them to have the business. So I just need some, I'm just confused.

Mr. Thompson: Absolutely, the three years of experience we had gotten some input from the public with respect to making sure that these vendors were established in the marketplace. So we took some of that input to heart and some of that came from the physician specialty societies. And so we decided, OK, maybe a reasonable criteria here would be three years. There was—

Dr. Grimm: How many vendors do you think you have out there that actually do this business?

Mr. Thompson: We received 15 responses to our request for information. We believe there is interest beyond those 15. The request for information was completely voluntary and in no way prohibited you, if you

didn't come in the request for information, it in no way prohibited you from eventually bidding, so we feel we have at least at a minimum a universe of 15 vendors with some very broad geographic scope and then in addition, as I said, suspect that there are others and looking at this decided from a business perspective decided there was no reason they needed to respond to the request for information, since they would have the ability to bid later. So the three years is open to comment. I think that would, if people felt that was too restrictive a criteria and they wanted to have that lessened that would be a very valid comment and we would weigh that in the Final Rule. That was the thought process. Kind of taking the input about you want to have somebody who's just freed of an entity overnight to get into this program. You want somebody who's established in the marketplace. That was the principle on the proposal. But again, seeking comment on—

Dr. Grimm: Yes, I guess my thought was if I wanted to get into this business, which sounds like it would be a [?] business for anybody who was thinking about, you know, how am I going to be this vendor, this government is setting up sort of an exclusive arrangement with them, and keep everybody out. How am I going to get into this? I'm never going to get into it. Three years experience.

Mr. Thompson: Right, and again, both in initial phase, open for comment, and also with respect to contracts run for three years, so these are not, this is not a forever situation in terms of who we would pick in the initial round. So there is flexibility and we seek comment on both the criteria that we would use for the first phase if you will, and then also there will be notice and comment on the second phase. And when we go out again. And that would be a valid comment to make. And you could even, people might comment it should be more, it should be less. Requirement shouldn't be there, and kind of weigh those for the fun.

Dr. Castellanos: Dr. Senagore?

Dr. Senagore: Yes, I would just follow up on that. I mean what you're really asking for with this proposal is a new skill set. This is really just [?] not necessarily procurement company. So to artificial to women it [?] years in the business. [off mike] We miss a skill set of individuals. It may be a [?].

Dr. Castellanos: Dr. Hamilton?

Dr. Hamilton: The way this is written, it is probably more restrictive than it really needs to be. And if you've had experience in—

Mr. Thompson: You don't often get that. [laughter]

Dr. Hamilton: If you've had experience in distributing pharmaceuticals, or if you've had experience in dealing with Medicare Part B, but not necessarily in distributing pharmaceuticals under Medicare Part B, it seems like that skill set, you might be eliminating some people who could really do a pretty good job.

Mr. Thompson: And definitely, it be worded poorly on the slide, and for that I apologize, but the concept here was experience distributing the drugs, not to Medicare.

Dr. Hamilton: Well that's what I mean. The way it says here, if you're not doing drugs to Medicare Part B, you're out.

Mr. Thompson: No, again, let me clarify that. You need to have experience distributing the kinds of drugs that Medicare covers. It is not that you have to have experience on the whole class of every single drug under Medicare Part B, but you have to have experience with drug distribution. So to say it another way you could have a drug wholesaler, who wants to play in this program, that has experience distributing injectible drugs. And that would be acceptable.

Dr. Hamilton: That just seems a little bit different than the way I read what you have here.

Mr. Thompson: Probably poor wording on my part. But the concept is that if you have experience doing drug distribution for injectible drugs.

Dr. Castellanos: Dr. McAneny?

Dr. McAneny: In the Proposed Rulemaking you discussed resupplying of drugs for emergency use. And I just have some questions about how that might occur. For example, I'm from New Mexico. People travel for three to four hours by car to get to the office to get their chemotherapy. If I then discover that their tumor has grown, and I wish to switch drugs, I have a drug that your CAP system has sent to me that's drug A, B, and C, and that's now the wrong drug, is it considered an emergency for me to use drugs out of my stock, assuming I can still afford to have such a thing, that, so that patient does not have to go home for another three hours have his or her daughter take off more time from work and pull the kid out of childcare to drive the patient back for three hours, and then come in on another day. Is that an emergency? Or do I have to tell my patients, sorry, you can't have this drug because this will get denied? Next question is who pays for that drug that I didn't use, drug A, B, and C to get shipped back to the CAP? Do I eat that cost of that shipping or does the CAP eat it?

Mr. Thompson: With respect to the first question, absolutely. If you have a medically, reasonably necessary kind of change in drug need for that day, you have the stock on hand, you have the ability to use that stock, and then have it replaced for what you use. Absolutely.

Dr. McAneny: Under the emergency—

Mr. Thompson: As long as you meet the other criteria—unanticipated change, vendor couldn't get it there in time. There's some criteria laid out in the rule. So yes, if you need, absolutely use your own stock, that's the concept behind the emergency situations where you'd be able to use what you had available, medically and reasonably necessary, and then the vendor would replace that if that's on the vendor's list of drugs that they use, that they would normally supply you with. It's a drug the vendor would normally supply you with.

Dr. McAneny: Can we use the CAP for some parts, and not the CAP for other parts, then?

Mr. Thompson: Sure, I mean if you, if you had say three drugs that you were going to administer and only one of them changed, you would use—there'll be tracking numbers for each of those three. So you'd use the two that you got from the vendor. You would apply those. And then for the one that you had to use from your stock, you would use that from your stock, and then the vendor would make you whole for what you used.

Dr. McAneny: That's not quite—what the question is that, and I still want to know who pays to ship it back.

Mr. Thompson: And that would be a valid comment. We did not, in the Proposed Rule, we sought comment on that particular situation, so your comment might be you think that the vendor should be forced to get the cost of taking that and getting it back. The other thing we envisioned was perhaps if it's a drug that you might use on another patient, the vendor would actually just be able to generate another prescription number if you will, another tracking number. And you would be able to use that and use the drug on another patient. So to the extent we can, we don't want to waste drugs. If in fact you have another patient that you're able to use that on, it might be simply a matter of talking to the vendor. The vendor creates a new order number, a new tracking number, gives that to you. You give it to that patient, put it on that patient's bill, the vendor does that. The other tracking number essentially becomes void and we move forward from there. So we're trying to become as efficient as possible in administering the system and minimize the drug wastage.

Dr. Grimm: Barbara can I ask you a question about how this is going to operate in your office? Because this is going to be a largely kind of a chemotherapy issue, as I can see it. Because most of us are dealing with

mostly outpatient sort of prescriptions. Are you going to have a Medicare refrigerator and a non-Medicare refrigerator?

Dr. McAneny: I'm going to do my best to stay out of the CAP system entirely, personally. However, if I can afford it—

Mr. Thompson: It's a voluntary program. But no, you don't need a separate refrigerator. We're not requiring separate physical inventory.

Dr. Grimm: You've got to track these things. Now you've got a vendor coming in from Medicare, or another vendor coming in and then you've got your sales person coming from the manufacturer coming in to bug you about these two, and you've got these two entities, and you're trying to keep your staff—OK, this is Medicare, this is, we got to buy separately from different ones. I'm going oh my gosh! This is a headache to me.

Dr. McAneny: I didn't enjoy the comments in there about how this was going to cut down my administration and then it would take me 15 minutes to fill out the form to set myself up with a CAP vendor. When I pick myself up off the floor from laughing at that, I tried to figure out how long it would take me to actually decide whether or not I could use a CAP vendor for this and to try to figure out whether or not I'm better off with ASP plus 6 for myself, on whether or not if I'm held liable for the shrinkage and wastage, that the vendor is not to be held liable for, or cannot be—

Mr. Thompson: The vendor is liable for that.

Dr. McAneny: It's supposedly their drug. If they have the ability to appeal that as my being a bad oncologist and not submitting all the data and wasting too much drug, if they can do those kinds of things, a couple of vials of Rituximab and I might be better off risking ASP plus 6.

Mr. Thompson: Just to clarify, the vendor's not able to do any of those things you just mentioned.

Dr. McAneny: The vendor, from what it looked like, as I was reading it in the Proposed Rulemaking, it looked to me like there was, that they could complain to Medicare, ask Medicare to counsel the physician on the CAP system if they weren't getting paid for things. So if I decided a drug vial is not handled properly, and it's clarified.

Mr. Thompson: No, just to clarify that. That discussion there is about if a physician were repeatedly had medical necessity denials for the same drug, that the vendor at that point could bring that to CMS's attention and say, this person keeps ordering this drug over and over and over again, and the local carrier keeps doing a

medical necessity denial on it. We have to ship the drug every time the doctor orders it. Can you intervene, maybe with some provider educations that the physician would understand that the situations that they repeatedly bill for the same drug that are being denied under medical necessity are likely to continue to be denied under medical necessity, just to make sure the physician understands what criteria are being applied. So we just didn't want to have a situation, because the vendor is required to ship the drug, where the vendor would have kind of exposure from the physician, who just continually order the drug and then have it denied for medical necessity. That was the point of that discussion.

Dr. Castellanos: I have just two very practical questions. I have a patient that has no co-insurance, and his inability to pay the 20%. Am I going to be able to go to the contractor and ask them to provide that drug?

Mr. Thompson: The contractor would be required to supply that drug to you. On the issue, if you're asking if the contractor would wave the co-insurance for that particular beneficiary, there's no separate requirement for a CAP vendor that's any different from a physician. So a physician can on a case-by-case basis—

Dr. Castellanos: So you're telling me the contractor—because these patients have ongoing treatments that last not just once, but every three months, for years. Even though the patient is unable to pay the co-insurance, from a financial viewpoint, the patient does not have a secondary insurance, that contractor will still bill that patient, but the contractor still has to provide that drug to that patient.

Mr. Thompson: That's true. We did not propose any mechanism for the contractor to deny supplying drugs to a beneficiary.

Dr. Castellanos: They cannot deny because of failure to pay the co-payment.

Mr. Thompson: We did not propose any mechanism for the contractor to deny based on that issue. We may get some comments from the manufacturers, but we did not propose—in our rule, we did not propose any mechanism for the contractor to deny the drug to the beneficiary.

Dr. Castellanos: Second question is that there are certain drugs that I use specifically, we talked last time about the bladder drugs, where I can't buy for ASP plus 6%. Am I able to do a hybrid system? I can buy those drugs from a competitor, but my other drugs that I may be able to make a profit on that I can buy through the manufacturer still?

Mr. Thompson: Under what we proposed, it would be all the drugs commonly furnished by urology, so in kind of the concept, the framework that we discussed in the Rule, it was all drugs commonly furnished by a specialty and the answer under that framework to that question would be that you would not be able to for drugs in a category, say some of these drugs, I want to continue to buy and be able to bill at ASP plus 6, and other drugs, I want to get from the vendor. Now the categories could be structured differently, and your comment might be I think that the categories should include these drugs and not these other drugs, and in that case you would elect to get the drugs in that category from the vendor, and these other drugs, you continue to bill at ASP plus 6. But the way we discuss it, and that would be a valid comment on the rule about how we would structure the categories. But the way the framework is discussed in the proposed rule, is all the drugs commonly furnished by your specialty. And once a drug is in a category, the physician cannot opt in and out for that drug. In other words, if the drugs in that category and you select the vendor, you must get the drug from that vendor.

Dr. Castellanos: For all drugs in that specialty.

Mr. Thompson: In that category. But the framework we discussed in the rule is by specialty, but other categories people may comment on other categories they may like to see, and under that scenario, if it's a drug that's not in the category, then you continue to buy and bill at ASP plus 6.

Dr. Castellenos: Dr. Grimm?

Dr. Grimm: Just for edification again, I'm walking through this process of what this vendor does. And if you can clarify for me again, and maybe I'm just slow on this. But it looks to me as if the vendor's going to go in and buy a contract with the manufacturer to buy the drug for $10. Right? Then they're going to come to you and say we're going to sell it to Medicare, presented in their bidding process at $15 so that they can make their $5, whatever it is. Is that right? Is that essentially what happens?

Mr. Thompson: Except, the average price for the category can't exceed ASP plus 6%. But other than that, you've got the concept correct. Manufacturer, we do not, the manufacturer and the vendor, or the distributor that the vendor gets it from, negotiate what prices they can negotiate. And then the vendor, the applicant, the bidding applicant, puts what they think is kind of their price to make.

Dr. Grimm: Does that ASP then, that the vendor contracted with, then go into calculation of the ASP?

Mr. Thompson: That's a question that we're seeking comment on. And legal analysis as well, about whether or not—

Dr. Grimm: Because that has really really significant affect on what that ASP is going to be.

Mr. Thompson: Sure, absolutely. I understand the question. Does the, the question is, to state another way, does the prices that are achieved under a drug competitive bidding program, do those feed back into the ASP system?

Dr. Grimm: Right.

Mr. Thompson: And that would be a valid comment to make for the Proposed Rule and whether they legally can or cannot be included in the calculation.

Dr. Castellanos: Are there any other questions? We certainly have time for recommendations. Do we have any recommendations that the Council would like to submit at this time, concerning the competitive bidding process? Dr. McAneny?

Dr. McAneny: I'd like to have PPAC recommend that CMS require that the CAP absorb the cost of returned drugs, unusable drugs, and that the CAPs must be willing to advance credit for drugs for patients with no ability to pay the co-pay.

Dr. Castellanos: Are there any discussions on that? Could you read that back to us please?

Ms. Trevas: PPAC recommends that CMS require that the competitive acquisition process absorb the cost of returning drugs, unusable drugs, and that the CAP advance credit for drugs for patients not able to pay the co-pay.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed?

Dr. Hamilton: I'm just curious. How do you determine whether or not a patient can make the co-payment?

Dr. Castellanos: I think from my practice experience, when the person comes into the practice—

Dr. Hamilton: Yeah, but how's this vendor going to know that?

Dr. Castellanos: I'm sure they're going to ask.

Dr. McAneny: To answer that question, most of these are recurrent treatments, or if you have mastastatic breast cancer, you have that treatment with one drug for a while, and that you have a treatment for another, and if they know that somebody is a Medicare/Medicaid dual eligible in most states, that means that you get 80% of the cost of that drug so instead of ASP plus 6, you're really getting 84% of ASP and so it's not going to take the vendors very long to learn that they're taking the same 16% hit on those drugs that we are. And I can

very easily see them putting language into the contract that says if the patient continues to not pay their 20%, we're not required to provide the drug. Physicians not being as good business people as other folks, we continue to treat those people over and over and over again. But I'm very worried about whether or not these corporations are going to do that.

Dr. Hamilton: I agree. I can't imagine how they would be able to deal with that on just kind of a small margin operation.

Dr. Castellanos: Are there any other recommendations? Dr. McAneny?

Dr. McAneny: Did we vote on it?

Dr. Castellanos: Oh, I'm sorry, we did vote on it, yes. That was, I apologize.

Ms. Trevas: PPAC recommends that the CAPs must be willing to provide drugs for off-label use when evidence-based medicine supports the indication.

Dr. Castellanos: Is there any discussion on that? Could read that back to us please?

Ms. Trevas: PPAC recommends that CMS require—do you mean the CAPs or do you mean the vendors?

Dr. McAneny: The contractor, the vendor selected to the process.

Ms. Trevas: OK. PPAC recommends that the vendors selected to the CAP process must be willing to provide drugs for off-label use when evidence supports such use.

Dr. Castellanos: I call the question. All in favor?

Dr. Senagore: Comment, you might want to recommend an adjudicating body for that, for the determining body. For medical necessity.

Dr. McAneny: Currently the answer that we got before was that we would go through the same process with the carrier medical directors that we go through now, but I can also see the situation where this corporation would decide that they don't want to take the risk to their cash flow, and they're not interested in going through the whole process.

Dr. Senagore: I just offered it as a friendly amendment. [off mike] Pursuant to current or existing CMS [policy?]

Dr. Castellanos: Do you accept that Barbara?

Dr. McAneny: Where do you want to put that in?

[off mike chat]

Dr. Castellanos: I think he's going to add that to the end of the amend—

Dr. Senagore: Read the original, and then we'll tell you where to put it in. Read it back so we can figure out where to put it.

Ms. Trevas: PPAC recommends that CMS require vendors selected through the CAP be willing to provide drugs for off-label use, when evidence supports such use.

Dr. Senagore: Based upon—

Dr. McAneny: I have language. And the vendor can use the established CMS process for determination of medical necessity.

Dr. Castellanos: Is that acceptable? Any further discussion? Could you read that back once more, please.

Ms. Trevas: PPAC recommends that CMS require vendors selected through the CAP be willing to provide drugs for off-label use when evidence supports such use. In such cases, vendors may use the established CMS process for determining medical necessity.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? Do you want to take a break for a second? I'd like to make a recommendation that PPAC recommend that the individual practicing physician has the ability to select on a drug by drug basis whether to participate in the CAP Program. Is there any addition or comment on that? Could you read that back please?

Ms. Trevas: PPAC recommends that CMS allow individual practicing physicians to have the ability to select on a drug by drug basis whether to participate in the CAP Program.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? Are there any other recommendations? Dr. McAneny?

Dr. McAneny: PPAC recommends that the vendor's price for the vendors selected under the CAP process not affect the ASP for the people opting out of the CAP Program.

Dr. Castellanos: Any questions or discussion on that? Could you read that back, please?

Ms. Trevas: PPAC recommends that the vendor's price for the those vendors selected by the CAP process not affect the ASP for those who opt out of the CAP Program.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? Are there any other recommendations? Seeing none, Mr. Thompson, and Ms. Black, we certainly appreciate your being here. I think it was a lively discussion. Hopefully you've gotten some important input from our Council and we look forward to further discussions.

Dr. McAneny: One comment before they leave? We, last time, were concerned about whether or not if there was a change in price that occurred after ASP was established, whether or not there would be any mechanism for a retrospective change and the answer basically came back that no, there isn't. It's set quarterly. It's already happened that one of the drug price increases has gone above ASP, so something that we currently, if you have to purchase it, and you didn't purchase enough in bulk at the beginning of the quarter to get you through that quarter, those smaller practices that can't do that are struggling with the issue of do we just eat a bunch more money every time we treat a patient, or how do we ethically manage this situation. And that's already occurred with a couple of drugs that I know of. And my other just general comment on the CAP system is that since the vendors are going to have the ASP plus 6 and that small amount of margin that's left on the drug, and the physicians—particularly, I'm worried about the large number of community oncologists that live in one, two, and three-doctor practices. They still are going to have to meet the OSHR requirements for a hood and proper ventilation and they've just increased those again, disposable various things, and properly handled waste, etc., etc., etc. Why under the CAP system, would any small practice elect to set up the infrastructure required to give chemotherapy and have all of that overhead be unreimbursed? I can assure you that the administrative increases, even though they were a large percent, that's still a large percent of the very small number, remains a very small number, even though those administrative codes have gone up, the cost of setting up a chemotherapy infusion area that meets all the of the requirements that we must meet is not paid for by any mechanism if you use the CAP program. Just a comment.

Dr. Castellanos: Any other comments? I'd like to take the opportunity now to break for lunch. I would like to try to convene back at 1:00 instead of 1:15 in the hopes that we'll have perhaps a little more time to discuss the Physician Fee Schedule.

Break for Lunch

Dr. Castellanos: OK, I think it's 1:00 now and I would like to call the Council back in session. Our next speaker is Mr. Steven Phillips. We certainly are going to be interested in hearing from him concerning the

Physician Fee Schedule. Mr. Steven Phillips is the Director of the Physician Practitioner Services, Centers for Medicare and Medicaid Services. It's good to see you again, Mr. Phillips.

Physician Fee Schedule Rule

Mr. Phillips: Thank you. Glad to be here. As you'll see from my handout, I don't have an extensive presentation prepared this. It's both a good time and perhaps a not-so-good time to be talking with you about 2006 Proposed Rule. Looking at it from the positive perspective, is that this is really the opportunity to have input as we're developing the rule and to take ideas that can be considered for inclusion as we prepare the rule. The downside is that we don't have a lot of decisions or, I can't really give you a long list of issues that will be presented just because of the early stage we are, in developing the rule. So what I've tried to do is just to touch on some issues that we will be certainly looking at as the year goes along. But I really wanted to take advantage of the opportunity of coming before you to receive your input and ideas that we could take away and consider as far as the 2006 Update to the Fee Schedule.

So I'll just on the next slide, the first item here, as you'll see, the 5-Year Review of Work RVUs. Last week we sent to the AMA's Relative Value Update Committee a complete list of codes for the 5-Year review that were over 800 codes on the list. The majority of them were recommended by physician specialty societies. The way the process began in last year's Final Rule, we published a discussion of our plan to proceed with the 5-Year Review, which is required by the statute, and indicated that we were soliciting public comments, identifying codes to be reviewed, as well as we published criteria that we would use in evaluating codes for potentially recommending to the RUC. And along with the over 800 codes, or included in the 800 codes were 171 that were recommended for review by CMS. In particular, we focused on high volume codes across specialties that have not recently been reviewed. Wanted to make a note that among the codes that were recommended by the specialty societies, we received comments from over 25 different specialty societies requesting that a large portion of the evaluation and maintenance codes should be reviewed as part of this 5-Year Review process. And to just kind of summarize, the general consensus among commenters was that the work dynamics of a typical E&M service have changed over time and the current route of values underestimate the work associated with these services. So that will be a big part of the ongoing review in this process. Just essentially at this point, as I said, the list of codes has been sent to the RUC. They will then contact the specialty societies to begin the process of surveying for input data to consider in their review of the codes.

Another issue in last year's Propose and Final Rules, we indicated that the American College of Cardiology and the American College of Radiology had submitted supplemental survey data that they wished to be used in the calculation of practice expense, but had requested that we delay using the supplemental surveys until issues related to the non-physician work pool could be addressed. And we agreed with their request and indicated that we would evaluate options for addressing the non-physician work pool going forward, as well as look at generally issues of updating practice expense data. I can tell you we're currently conducting analysis of potential alternatives to the non-physician work pool and plan to include in the Proposed Rule discussion of future options to proceed for updating the practice expense data on a more systematic approach going forward.

Really other than that, things are still under discussion and under development and I'm sure that you all have issues that you would like to raise and discuss. My thought at this point was to just open it up and we would receive input from you to consider as we go forward on the Rule.

Dr. Powers: The issue of the evaluation of management services are of importance to those of us who are in relatively nonprocedural specialties. And if I'm understanding correctly, the last time that this was reviewed, recommendations were not necessarily accepted by CMS for increases. So I think at this point it's important to understand that there are some specialties that are in jeopardy of disappearing to some extent. Because people aren't going into those specialties because of the stark differences in reimbursement for those specialties. So as a recommendation, I would ask that PPAC recommends CMS accept and implement recommendations for increases in work RVUs for evaluation and management services that will be coming out of the Relative Value Update Committee.

[Seconds]

Dr. Castellanos: You making that as a recommendation? It's seconded. Is there any discussion on that recommendation?

Dr. Azocar: When you talk of organizations are you also including primary care associations within those specialties?

Mr. Phillips: Yes, yes, that's, as I said, we received on the issue of the E&M-codes, we received recommendations from over 25 specialties. So any of the individual specialties or subspecialties that submitted comment.

Dr. Castellanos: Is there any other discussion on that recommendation? Would you be so kind as to read it back to us please?

Ms. Trevas: PPAC recommends that CMS accept and implement the recommendations for increases in work RVUs for Evaluation and Management Services that come from the AMA's RUC.

Dr. Simon: Dr. Castellanos? Just for point of information and education to the Council, when specialty societies submit CPT-codes for consideration and review under the 5-Year Review schedule that's performed by the AMA Relative Value Update Committee, the RUC will make determinations, number one, as to whether those codes are worthy of consideration. And then, two, if those codes are worthy of consideration, then the RUC will review those codes with its usual level of scrutiny as it does to all the new and existing codes that are brought to it. The RUC then will make recommendations to CMS which occurs on an annual basis when new codes or revised codes are submitted to the RUC for review and consideration. And those recommendations are usually sent to us in the summer. And then the agency will then review those recommendations and make the appropriate adjustments and refinements as necessary. Historically, CMS has accepted over 90% of the recommendations from the AMA on RUC-codes that are brought to the agency after having been reviewed by the RUC. So I just want to share the process with the Council in that those codes, by the Primary Care Coalition, are brought to the RUC, and they're not brought to CMS. And the RUC will review those codes and make determinations as to evaluation of those services.

Dr. Castellanos: For completeness sake, let's go ahead and read that back one more time.

Ms. Trevas: PPAC recommends that CMS accept and implement the recommendations for increases in work RVUs for Evaluation and Management Services that come from the AMA's RUC.

Dr. Castellanos: And that's been seconded. Now I'm going to call the question.

Unidentified speaker: Could it be in the spirit it would be that you would accept the recommendations of the RUC, because it may or may not be increases? Depending on what the RUC decides to do. But that's out of germane at this [pass?]

Dr. Castellanos: Do you want that as a friendly amendment to this?

Dr. Powers: Yes. That's fine.

[off-mike chat]

Dr. Castellanos: Can you repeat that? We're having a hard time with mikes—

Dr. Senagore: I think we just need to take out the work increase. If you could read it one more time, then—

Ms. Trevas: PPAC recommends that CMS accept and implement the recommendations regarding work RVUs for Evaluation and Management Services from the RUC.

Dr. Senagore: She got it out. I think she got it out.

Dr. Castellanos: May I call the question? All in favor? [Ays] Opposed? Do we have any other questions that we want? Dr. Urata?

Dr. Urata: What's the timeline for getting out the [rope?] By next meeting? By our next PPAC meeting or is it something longer, or—

Mr. Phillips: When is your next scheduled meeting?

Dr. Urata: Three months.

Mr. Phillips: Three months.

Dr. Castellanos: May 23rd.

Mr. Phillips: OK, it's probably a little bit longer than that. Last year, we published our Proposed Rule I believe August 8th. We always are trying to beat last year and this year around, where we're hoping to be considerably earlier than that. But I don't think by May that it will be out. It certainly will be much further along than we are now.

Dr. Urata: And so we'll be able to comment on more substance, perhaps by then.

Mr. Phillips: Right. We will be further along in terms of our process of developing what's going to be in there and can better assess issues that we can go ahead and give folks a heads-up about at that point.

Dr. Urata: Great.

Mr. Phillips: But again, I would reiterate that this kind of raising brand new issues at that point is problematic, particularly if there is, when there's a lot of analysis that's involved. So one of the advantages at this point is any things that folks would want us to look at, this is probably the best opportunity for that.

Mr. Kuhn: Perhaps our best shot for that is to interject here, is our August meeting. Perhaps, again, you know, depending on when we get this published. But that would probably be the most likely time when we would be in a position to for all of you to really opine specifically what's in the Reg.

Dr. Castellanos: Dr. McAneny?

Dr. McAneny: Given that we got the 1.5% increases for each of the last couple years, would that just end to where the SGR is already. This means that the Physician Fee Schedule would be slated for about a 5.5% decrease unless something remarkable happens. So I'm wondering whether or not CMS has any plans to look at something remarkable, such as the idea of taking the physician incident to drugs out of the SGR and doing it retroactively, which we're told would fix the problem and get rid of this decrease that we're headed into. You know, if we had a 5% decrease every year from 2006 until, for 5 more years, and it's a 30% decrease in physician fees, there aren't any of us going to be able to afford to continue to take care of Medicare patients.

Mr. Phillips: That is certainly the big issue. And of course that's not something that at this point we're prepared to say we're going to do this or that. I mean it's something that's being looked at by certainly the administration, Congress, MedPac, CBO, I mean everybody is looking at this because of the magnitude of the issue. As far as I know that you mentioned taking drugs out of the SGR retroactively, that is an issue that our legal counsel is looking at in terms of evaluating whether we have the authority to do that. And that makes a difference in terms of not taking the drugs out respectively, one would still not result in positive updates for several years. But you know, as I say, that is an issue which we certainly are focused on and will take Council's concerns there as well. But it's going to be an ongoing issue.

Dr. Castellanos: Not to answer the question. Mr. Kuhn, do you have any comments concerning that, or Dr. Simon, do you have any comments concerning the SGR?

Mr. Kuhn: I think Steve phrased it right. I think the administration continues to look at the issue in terms of what is our legal authority to go back and retroactive. Many of the physician groups have asked for us to go back to '96, '97, to retroactively remove the drugs from the SGR. Our legal counsel continues to look at that. And actually, recently, some of the various physician groups have come forward with differing legal opinions, so that we can have an even more thoughtful engagement on that, which I think is very helpful. Steve's also absolutely right. If we did it on a go-for-it basis, it really doesn't yield you anything until 2011. And so the real issue that a lot of people are looking for the agency: Can we do it retroactively and that's something that our legal counsel still needs to opine for us on that.

Dr. Castellanos: Thank you. Dr. McAneny?

Dr. McAneny: Just a follow up question. If one makes the assumption that your legal counsel tells you that you cannot retroactively take the physician drugs out of the SGR, and you're looking at giving a 5%

decrease, 5% and change, across the country for physicians. Have you done any forecasting on what that would do to participation in Medicare, and if that goes on for years and years? Have you done any forecasting as to how many physicians you think would remain in Medicare? And does CMS have a Plan B, then, to try to keep physicians in Medicare?

Mr. Phillips: Well, I mean, the only real history that we have, the kind of inform that type of analysis is when there was a negative update in 2002. And the estimate is that actually total spending did continue to go up, which was kind of fed back into the SGR problem. Kind of volume increase, despite the reduction in the fee. As far as the level of the adjustment—I believe the present budget was a 4.3% negative update, but that's still bigger than in 2002. So it's still is somewhat in question how much you can rely on the history from 2002 of what would happen, and certainly going forward for multiple years, you know, I am not aware of anybody who has done that analysis. It is subject to so many variables in terms of what point, is it just no longer possible to make that up, or and as far as a Plan B, no. Not that I'm aware of.

Mr. Kuhn: Nothing further. We haven't done any analysis like that. Steve said, all we have is the historical perspective here and right now, our focus is to work on getting out this year's proposed regulation and that's where our attention is focused at the current time.

Dr. Castellanos: Are there any other questions? Does anybody, any other Council member have any other questions? That surprises me. OK. At this time, does the Council have any recommendations that they want to put forth concerning the Physician Fee Schedule Rule? Dr. McAneny?

Dr. McAneny: This one's on the fly, so hopefully it comes out relatively coherent. If not, you'll have to fix it. PPAC recommends that CMS begin a projection of what would happen to Medicare patients' access if we are confronted with the proposed decrease in fee schedule from the SGR; and develop a plan of action in the event those projected decreases. That wasn't very coherent, but, I should write it first.

Dr. Castellanos: Is there any discussion on that? This isn't a discussion, but it's a comment. I was a meeting this past week, concerning the workforce, specifically in my specialty, urology. And considering the landscape what's happening, there's about 41% of the urologists in the United States that are now 55 years or older. And taking that into consideration and taking into consideration the dramatic financial changes we've had with incident to drugs, AWP, ASP, etc. and now with this proposed SGR cut, there's a tremendous, I shouldn't say undercutting, but a lot of physicians are going to think about retiring early. Especially in the face of

rocketing malpractice premiums. I think you can use historic data to 2002, but the playing field has changed. At least in our specialty, and we're already at a shortage. And I'm not saying that we're going to have a precipitous dropout of Medicare, but it's something that certainly needs to be considered. Are there any other comments? Dr. O'Shea?

Dr. O'Shea: I'm just going to reiterate what I had brought up before. PPAC recommends that CMS use its administrative authority to remove Medicare coverage—

Dr. Castellanos: Can we hold that just a second because I think we have a motion already on. We're just discussing Barbara's motion.

Dr. O'Shea: Comment on that, then, also. That the same does apply. That we do need some more forward thinking down the line. That the physicians cannot abide by these changes unless there's some type of administrative oversight and foresight that sees that we are heading towards a wall, and you will have more physicians leaving Medicare provider practices, and you'll have more people that will just have to go to emergency rooms, say. And if you think that the services are kind of expensive now, they're going to become more expensive later on if we don't have some kind of other services.

Dr. Castellanos: Dr. O'Shea, would you care to discuss some of the personal comments you mentioned about your practice, as a practicing physician, and being the only female internists in your community, how this may impact you?

Dr. O'Shea: As Dr. Castellanos has said, I do internal medicine in a mostly rural area and being the only woman internist there, I have an ability in a way if you might say, to choose, and if it's going to behoove me to service my patients differently, depending on their insurance, it's going to happen kind of naturally, just to keep the door open. And I'm a small practice, actually, just two physicians and myself. So you have to understand that although we may be committed by our Hippocratic Oath to provide services and that we have committed honestly ourselves, we have to become better business people, just like you are, and so you're going to find more diversion of Medicare patients away from certain practices, and they're going to have to go more towards clinics. And maybe even clinics aren't going to be always available to them. So they're going to seek, they're going to have less care, which will end with I think more ill elderly population.

Dr. Castellanos: Are there any other comments concerning the motion that's on? Dr. Azocar?

Dr. Azocar: I just wanted to if you allow me a moment to present a view that will reinforce these concerns. Basically, we just want to present a brief picture of what a primary care practice in the inner city, whether it's Trenton, New Jersey, Bronx, New York, or Springfield, Massachusetts. Primary care practice is heavily, I mean, most of the patients are Medicare and Medicaid patients. I'm talking about 70, 80%. This is the population usually we call under-served. It's a lot of minorities, although in numbers, they are significantly very high. In the country. It's a population that is very sick with a lot of risk behavior for many diseases with a high prevalence of HIV, Hepatitis C, Hyper[?], everything together, diabetics, hypertension, coronary artery disease. These are people which are very complex as compared to somebody who just go for the annual physical exam. This is what we face, as primary care physicians all over the country, mainly in the inner cities. And I don't know about the rural part, rural areas, but I think there may be some similarities. These are practices which are in a very difficult time financially. Which are extremely making the best they can, unable to afford a few things that will improve their services, such as education, advice for somebody who is a diabetic. These are practices which are, I would say, in danger of extinction. What do people do in those practices, in those areas? They are heavily users of the ERs. And we all know how cost effective to bring those people to having a primary care physician. I am very concerned that all these decreases in the return for this group of physicians, and obviously for all of them, but for this group of physicians particularly, is going to put a lot of the current use of Medicaid/Medicare population, is going to leave them without that option—the healthcare possibility—because the issue is not only not accepting them, because when you depend so heavily on like you depend 70% of your population from Medicare/Medicaid, the option would be close your business. So I think that the situation is very critical. Just to give you an idea, because I realize that the issue is very critical, and just to be, I endorse very much this proposition on projecting and seeing what we're going to do.

Mr. Phillips: Yes, I guess I would just reiterate that the certainly the administration, as well as the Congress and others are I think understand the magnitude of the issue that we're facing and are focusing on this.

Dr. Castellanos: Are there any other comments on this motion? Dr. McAneny?

Dr. McAneny: I read with some degree of surprise the MedPac article on, or their posting they did in February on physicians, and I was surprised to see that they felt that there really was not an access problem, because in my own practice, I get asked probably by ten Medicare patients a week if I will help them find a primary care physician. And I ask them if they've tried and if they've called. And they say, yes, I've called three

or four times. Did you call 1-800-MEDICARE? No, why should I? I just get put on hold. I've sent them out and told them there's the phone, go call them and tell them you're having trouble. And I'm hearing a disconnect between what I'm reading in MedPac and what Dr. Azocar just said and what I'm hearing in my own practice in terms of access now. And it may be that they're asking the physicians in his clinic areas who are accepting Medicare, because their entire practice is Medicare. But I think that if we end up with these fee cuts, we will not be able to have the AMA use political capital to go to the Hill again, and get that increase for us again because they can't continue to use that political capital to bail out Medicare, and that's sort of what's been happening over the last several years. So I think that just saying we've got to work on this year's, get this year's posting out is not sufficient. I think we have to be more forward looking, and we have to come up with some sort of a long range plan. And if your lawyers tell you you can't get the drugs out, or your actuaries tell you that won't fix the issue, then I think we're down to the wire to where CMS is going to have to use its political capital to say, Go to the Hill and fix the SGR. Get rid of it, and put in a system that will actually reflect the cost of practice and keep physicians able to see their Medicare seniors.

Dr. Castellanos: As a comment, when some of us addressed the carrier medical group when they met a year or so ago in Baltimore, and I addressed the issue of access to care, and one of the comments I had, well, from a carrier medical director, he was from Hawaii, he mentioned that he, as a physician, and his family, were having trouble getting access to care. So it's not just in the inner city population. I see it in my practice. I see it where I cannot get patients in to see an internist. I think we're going to be facing a real crisis of access to care unless this issue is dealt with and dealt with effectively. Are there any other comments? Can we read the motion back?

Ms. Trevas: PPAC recommends that CMS begin projecting the affect on Medicare beneficiaries' access to physician care, if the proposed decrease in the Physician Fee Schedule as a result of the SGR comes to pass, and that CMS develop a plan to prevent decreases in physician participation.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? Dr. O'Shea, you had another? [off mike chat]

Dr. O'Shea: PPAC recommends that CMS use its administrative authority to remove Medicare-covered physician administrated drugs and biologics from the physician payment formula, retroactive to 1996.

Dr. Castellanos: Is there any discussion on that? Can you read it back, please?

Ms. Trevas: PPAC recommends CMS use its administrative authority to remove Medicare-covered physician administered drugs and biologics from the physician payment formula, retroactive to 1996.

Dr. Castellanos: The motion's been made and seconded, I'll call the question. All in favor? [Ays] Opposed? Are there any other recommendations that we want to present at this time concerning the Physician Fee Schedule 2006? Mr. Phillips, we certainly appreciate your being here. We're looking forward to the Rule's being published, and more commentary and Sir, I'm sure you're going to be here a lot more times. [laughter] [chat]

Dr. Castellanos: We have a short break now. The next two speakers. We're just running just a little ahead of schedule and the next two speakers are on their way, so why don't we take a ten-minute break and we'll meet back here in ten minutes.

Break

Dr. Castellanos: I'd like to call the meeting back in session. If we could all sit down. Our next speakers are going to be talking about the Medicare Prescription Drug Coverage, Provider Education, and Outreach Strategy. Ms. Robin Fritter and Ms. Suzanne Lewis are both Senior Analysts in the Provider Communication Group within the Center for Medicare Management at CMS. They have led the agency's provider education outreach efforts for the Medicare Approved Prescription Drug Discount cards and the transitional assistance. They've also handled multiple high-visible national campaigns, directed towards the 1.2 million Medicare physicians and providers. Ms. Lewis and Ms. Fritter will be presenting the Medicare Prescription Drug Provider Education and Outreach Strategy. They've asked us to give them feedback on CMS's current provider communication methods. What's working, what isn't. They would also ask us to try to suggest other ways that the agency perhaps can get more effective information into our hands as practicing physicians. Ms. Lewis and Ms. Fritter?

Medicare Prescription Drug Provider Education and Outreach Strategy

Ms. Lewis: Thank you very much. I'm Suzanne Lewis. And it's my pleasure to be here today, and I really look forward to hearing your comments. And as Dr. Castellanos said, Robin and I are not technical experts on the drug benefit, and we are very open and willing to listen to your comments or any of your frustrations you may have regarding the technical aspects although that's not something that we have authority over, or something that we work with on a day to day basis. Our responsibility is to take information about the Medicare

Program and to develop educational tools. Products, mostly electronic products, that we then push out to our various audiences, and I'm going to explain that mechanism today.

So what we're going to talk about is a little bit about the program, the new drug coverage, mostly focused on what we have developed. And it's a work in progress, so we are open to your comments and suggestions that we can incorporate into our strategy, and then we have at least half the time if not more than half the time allotted today we want to hear from you. We have specific questions from you, but we also want your general feedback as well. I want to explain to you what Robin and I have been up to for the past 18 months. We were assigned to be the leads for the Provider Education and Outreach Strategy for the drug card and Transitional Assistance Program. And boy did we have a lot of lessons that we learned through that process. It was the very first time in the agency's history where the entire agency had to work together. We worked across all components to pull together a huge education campaign for not only the people that have Medicare health insurance, but also for the 1.2 million physicians and providers and there's another area within the agency that had to work with the states and educate the states. And so we learned a lot of lessons, and we've incorporated what we've learned into our new strategy. And I'll explain to you as we go along what we learned and how we're changing our strategy.

So the drug benefit—have any of you read the regulation yet? Have you seen the regulation? Is it something that you would do? I think probably maybe parts of the media would. Very complicated, but that is available for you to actually look at and order a copy for yourself, and I will tell you how you can do that later in the slide presentation. But this new prescription drug coverage is effective January 1, 2006. Prior to the effective date of the drug coverage, there is a Medicare-approved prescription drug card, discount cards and Transitional Assistance Program. And that was meant to be a temporary program, to help people with Medicare offset some of the costs of prescription drugs. It's meant to be temporary, 18 months, and so that should end of 2005 when the new benefit takes effect. The new benefit is going to allow for assistance with prescription drug costs. We are not the technical people that can explain the program to you thoroughly, however, it's my understand that there will be someone that will come and address the Council maybe at your next meeting, to give you the details of the new program. But we do know from experience, and I'm sure you do, too, that when your patients who have Medicare coverage start getting information from the Medicare Program, when they start seeing things in the news, they will probably mention this to you and ask you for your opinion of it, what do you think about it?

What is this? I don't understand it. And we just want to make sure that you realize that we are not having the expectation on the physician community to educate the Medicare beneficiaries about this. What our campaign is all about is making you aware that this is a program that's available. And we also want to make you aware of where to refer your patients to get more information. Because there are people out there who will have the responsibility of counseling patients, Medicare beneficiaries, on this new benefit. We do know that your thoughts about this program, how you feel about it will influence your patients' choices and so that's something that we want to talk with you a little bit more, too, today. And that when your patients come to you and ask you questions about this, that this is an opportunity to let them know where they can get the information. Thank you.

So the first lesson that we learned in the drug card campaign was that our audience that we identified to educate was much too narrow. We identified physicians and other health care professionals and pharmacists and other pharmacy professionals, such as pharmacy technicians. And what Robin and I learned as we went to other advisory groups and explained our strategy was that we missed out on a huge audience, and these were our institutional providers. And the staff at the institutional provider facilities, such as the discharge planners, the social workers, and what these facility representatives told us is that we see a lot of Medicare beneficiaries everyday. We have clinics. We have waiting rooms. We're willing to give out materials through these facilities, and our discharge planners could certainly give out brochures and other information, and so don't forget about us. We want to help. And so that's why we have incorporated this new audience into this campaign.

And just so you understand how we run a campaign from CMS. On big national campaigns, how we get out information out. Robin and I both work at Central Office in Baltimore, Maryland, and in the provider communications group, we work in the Division of Provider Information Planning and Development, part of what we're responsible for is actually developing the products, or the materials. We deal with national outreach, to national provider associations. And we have what is called a Provider Partnership Directory. It's something that is growing. We currently have a list of over 50 professional associations that are connected into our directory where we push out information to them, and they in turn push the information out to their membership. Our directory does include quite a few physician associations, including the AMA and the National Hispanic Physicians Association, the National Physicians Association, and a host of specialty associations. And I'm not sure if that's something that you can give us feedback on toward the end of this talk is if you are seeing things

from CMS, from the Medicare Program in your own association's communication with you in the newsletters, if you visit their website, are you seeing that information?

So we have the National Information Dissemination, we also have ten regional offices at CMS. And these regions develop their own partnerships with state and local medical societies and associations. The agency also has an exhibit program that has really grown by leaps and bounds in the last couple of years. Last year, the CMS exhibit participated in over 80 national association meetings and conferences around the country. It's the regional office staff who actually man these exhibit booths. And they're there to interact with the conference and meeting attendees and also to disseminate our information. And so if you're at a national association meeting, you'll probably see a CMS exhibit. And the information that is at that exhibit comes from our office.

So the third tier within our three-tier approach is our Fee for Service contractors. We have over 50 Fee for Service contractors who are responsible for processing over a billion claims, Medicare claims per year. And they also are responsible for educating individual providers. So you may notice that you get in your correspondences from your carriers, they'll offer in-person training or they'll actually if you register for their list serve, which is something we highly encourage you to do, is to register for your carrier's list serve so that you can get information, or whoever you identify in your office and your practice to get that information, would come to you to keep you in the loop on what's happening. But these fee for service contractors are very involved in getting information out to you.

So what I want to talk about now is what we're actually doing for our campaign. We've talked about how we have structured it in our three-tier approach, and I'd like to ask you now if you could show me by raising your hand, if you've ever heard of or are familiar with MedLearn Matters articles. I see a few hands. Great. Great. MedLearn Matters articles have become very popular and it's a very good way for you to stay in touch with what's happening with the program. They're very simple, easy to read articles that are based on change requests within the agency. They've become so popular and so trusted as a good source of information from the Medicare Program. We're developing a series of national articles on the drug benefit, specifically for the audiences that we identified, physicians and other healthcare practitioners as well as pharmacists and pharmacy techs, and also the institutional providers. And we've, actually when I had to submit these slides, we only had one article released on the drug benefit. We actually have two that have been released. We're on a track of having about one article per month at this point, but there may be additional as the campaign heats up. The very

first article was released in the end of January. The second one was on Facts Regarding the Medicare Prescription Drug Coverage and that was released at the end of February. So if either your practice manager or if you're interested in keeping abreast of the Medicare Program yourself, I highly recommend that you bookmark the website that's on the slide, to get to the MedLearn Matters articles. We also have a list serve that you can register, and you will get an email letting you know each time a new MedLearn Matters article is released.

Another product that actually we're not developing—Oh, OK, we're going to talk about distribution. How we get MedLearn Matters articles out to the provider community. Your carrier, your contractor has a newsletter, and that's something that you should be receiving. However, we do understand that in some cases, you may have the address of the person who handles your billing that may be receiving this and that could be an issue. But there is a way for you to get these directly and that is to get to your contractor's website and register directly for the list serve or for the MedLearn Matters list serve that I just talked about. We also send these articles out. They're all electronic. Through the professional associations, so through the AMA and your specialty associations would be receiving these articles. They'll either reprint the entire article in their newsletter or print a link to how you can access it. And it's also a link on their websites. We also have at CMS provider audience web pages. At CMS.HHS.gov under professionals, there is a list of specific providers, and each provider type has its own web page, which we call an audience page. So if you're a physician, everything that a physician would want to know about Medicare, we have listed on that page, and links to the information that you'd need. This is a really good resource for you to let your office staff know if you rely on office staff to keep you posted on the most current information. Each CMS regional office also has a web page where they have a list serve, if you want to get more local information, local medical review policy information, you can get this way. And they also have an electronic newsletter. And we talked about the CMS exhibit program. And through this program, we provide hard copies of our MedLearn Matters articles to distribute.

The Drug Coverage Partnership Kit is actually being developed by the Center for Beneficiary Choices, or CBC. And they are developing these kits. Actually, it's one kit that has information that will really help people who want to be in the role of counseling beneficiaries on this new benefit. And so the beneficiary advocacy associations are very interested in this kit. However, even though you may not want to take an active role in counseling your patients on this, and we don't expect you to, if you have nurses that work with you or front office staff, or anyone else in your practice that you would like to have a little bit more information about

the drug coverage benefit, they can actually get a copy of this kit. The web page that we have listed on slide, the partnerships page, is an excellent cite for that kind of information. And actually we have on the slide that it's available March 31st, well it's going to be available April 1st. So one day late. But if you go to that web page, beginning April 1st, there will be information on how you can order a hard copy of the kit. However, an electronic copy of the kit will be available. This isn't meant to be overly detailed. It's really good basic information on drug coverage, written in layman's language that you can use to explain the benefit to people with Medicare. For the drug card campaign, we developed posters that could be displayed in clinical settings. These posters were developed for beneficiaries that you could display in your office, in your waiting room if you have a clinic and the message on the poster was if you'd like to learn more information about how you can save money on the cost of prescription drugs, call 1-800-MEDICARE. It also gave the URL for Medicare.gov. These were very popular. And we are actually developing these again. This time, CBC is working with the Social Security Administration to develop these posters, and they were available in both English and Spanish. And this is something that if you get on our list serve, if you're on your contractor's list serve, your carrier's list serve, you will be notified when the poster's available, and you can call an 800 number to order the poster, or order it through the MedLearn website. And again, all the URLs are going to be on a later slide.

How you can get and stay connected to what's happening in Medicare. Again we talked about information from your Fee for Service contractor, if you're a physician then it's your carrier, and your professional associations. Really stay connected with them. They are all getting the same information from the agency, and we push that out and they automatically, since everything is electronic, you get the information very quickly. We've also recently launched a web page specifically for Medicare physicians and providers on the drug coverage benefit. And the URL is listed on the slide, the second bullet. And right now it's not populated very much because we're still developing materials. But as the year progresses, there will be more and more information on that web page. We also have a specific list serve just on drug coverage. If you register for the MedLearn Matters list serve, you will receive an email notification every time a MedLearn Matters article is released. And they're released on all subject areas of Medicare that are of interest to any Medicare provider. So you do get quite a few emails. But if you are specifically interested in information on drug coverage, then you would, actually there's a list of topic areas that you could register for information on that particular topic and you'd want the drug coverage topic.

I also want to see by show of hands, please, those of you who have participated or at least listened to a CMS Open Door Forum for physicians. A few of you have. OK. This is an excellent way, for those of you who are not aware of this or who have not participated, this is an excellent way for you to have access to CMS leadership on the hottest topics in your field of interest. And these are, there's a schedule for Open Door Forums that's on CMS.HHS.gov/Opendoorforums, and I think for physicians, it's once a month or once every other month, and you can listen to the hot topics. If you have a particular topic that you're interested in, a difficulty that you're having with your practice, something that you really like to see changed about Medicare. We also like to hear about things that you really like that we're doing, that you'd like us to continue to do, this is the mechanism by which you can get your voice heard directly to the leadership. And so it's something that we highly recommend.

These are a list of the key websites that Robin and I determined would be most important to you as physicians. Again, the first one is Medicare Reform. So that's going to keep you posted on all the legalese. The actual regulations, and they're like, and I didn't bring them with me, but I can do my strength training with my regs that I carry around. They're like little phone books, and so if you're really interested to read about what the comments were in the Rulemaking process, you can make comments on the Proposed Rules, and it's interesting to see what kind of comments specialty areas had on the Proposed Rule and what the CMS's comments were to those. And the drug coverage page that we mentioned, MedLearn Matters, how to get on the list serves for various topics, the mailing list, the partnerships webpage, where you can order your counseling toolkit and Medicare.gov, which is really the layman's language webpage that has information for Medicare beneficiaries. What I really like about Medicare.gov is they take very complicated Medicare information and develop them into fact sheets and booklets that can be understood by the Medicare beneficiaries. So you can actually download some of these products and have copies made and have them in your waiting room. But there's also an 800 number listed, where you can call and order limited quantities of these materials to have in your clinics and your waiting room to give to your patients who have Medicare coverage. So our main message is to the physician community is that we don't want you to feel overwhelmed that it's your responsibility to counsel your patients on this new drug coverage, that the agency is developing lots and lots of materials to help Medicare beneficiaries understand the benefit, and there are plans for direct mailings to the beneficiaries. And one of the comments that we received is the provider said, well, we would like to know when you're sending something out to people with

Medicare, because when they come to us, and talk about it, we'd like to know what it is that we're referring to So that's something that we can send out through our MedLearn Matters articles. We'll keep you apprised of that through list serve notices as well. Also our message to you is that we really see your role more as referring your patients to resources where they can get information, because we know that your time is very limited and you want to spend the time with your patients, working through their medical issues and not as a Medicare counselor. As insurance counselor. So the big message that you're going to see in the posters, in the MedLearn Matters articles, are: Please refer your patients with questions to 1-800-MEDICARE, where we have trained customer service reps who can handle their questions and help them, and for your beneficiaries who are computer savvy, they can go to the Medicare.gov or if they have their daughter, granddaughter, grandson, who can help them with that, that's where there's also information on the benefits. And what I'd like to do now is turn the mike over to my colleague, Robin Fritter, who is going to talk with you about what feedback we've gotten from the provider community so far on this campaign and she'll also lead the discussion in getting feedback from and she also has questions that we want to ask you about our campaign and other ideas that we have. Just to see if you think they may work. So thank you for your attention.

Ms. Fritter: Thanks Suzanne. My name is Robin Fritter and I thank you very much for the opportunity to talk with you today about our campaign, our outreach strategy regarding the drug coverage. And also to hear your feedback, listen to your input, listen to suggestions and further refine, add to, and enhance our communication strategies. We have a very large audience to reach, 1.2 million providers. And as you can well imagine, when the beneficiary operational side of CMS, we have an even larger audience to reach, 42 million beneficiaries. So working together is critical because we realize that those beneficiaries coming into your offices, looking to you for guidance, for suggestions, sometimes even for help with decision making, can be extremely overwhelming and we are sensitive to the fact that you have a lot to do in a very short amount of time and your utmost concern is to deliver the best clinical care that you can and not to be as engaged in counseling and educating beneficiaries. And we have clearly heard from providers, physicians, staff who work for physicians, and who work for group practices, that physicians are not expecting to provide some type of service to beneficiaries unless they're going to be reimbursed for it. And our expectation is not that you are going to be delivering some type service, and not receive reimbursement for it. However, we know that patients have a trust, an inherent trust, in their physicians, and they look toward you and pay attention to what you say to them, and in

that very short amount of time, if the one message that you can deliver is, You know, you're right, there is this new prescription drug coverage program coming from the Medicare Program. I really don't know a lot of the details about it myself, but there's a pamphlet out in my waiting room. Why don't you pick it up on your way out? Or right now the best I can offer you is to call 1-800-MEDICARE or get your husband, your wife, your daughter, whoever it is who's helping in providing the care to that person to look on that computer to that Medicare.gov website. I understand they have some good information there. And there's more information to come. If the very least that we can ask physicians to do at least now in this point of the campaign is to delivery a positive message that this potentially could help your patient save some money on their prescription drug cost, that's a win win situation for you, and for the beneficiary and for us, actually.

Like I said, because they trust what it is you have to say to them, chances are, they may actually follow through with making that call or getting some help by looking at the website or picking up the pamphlet or looking at the poster, once we have this materials out and available to you. So as I said, we have heard that physicians really don't have time to counsel patients on this new prescription drug coverage program. However we have heard that in some settings, in some specific areas, in some settings like in the rural area, certain clinicians do want more than the basic information about the program. Or they know that they or perhaps that one other staff person, will have to engage in some form of further counseling or further educating of their patients. So we know that there is sort of a range of informational needs within the physician community from the basic to the more detailed, so we want to make sure that what we will be providing access to that information to you so that you can get what you need. You just want the basics, you want a little bit more or you want the detailed packets, we want to make all of that available to you to meet whatever your needs are. We also have heard from the physician community that they expect the pharmacist to counsel patients about this. We won't be doing this, but the pharmacists are going to take care of it for us. So we've heard that. We certainly know that pharmacists engage in some information sharing, in some dialog, with their patients, with their customers, with their clients, when they show up at the counter to say, well, here's the prescription for the medicine my doctor told me I need, and the pharmacist is a little more savvy perhaps and says, well, what plan are you signed up with? Or how can we juggle and how can we get the best price for you according to whatever your options are, in terms of the plans that you are a member of. So we know that the pharmacists are definitely an audience we need to reach with information. And we're also hearing from them that they may want sort of a basic to the

detailed. We've heard somewhat from pharmacists that they expect that they will need to know a little bit more about the program, because they're serving in more of an advocacy, counseling type of role with the Medicare beneficiaries. But like I said, we've heard from physicians saying, well I won't have to do it because the pharmacists will, or I'm expecting that they will. And I'd like to hear more from the Council when we get to that part as to what your perspective on that is as well.

And thirdly, we have overwhelmingly heard from people who you employ; your front office staff, your practice managers, financial planners in the hospital setting, nurses who work for physicians that they are the ones in your offices who, if there's any information that we want them to share with beneficiaries, that they will likely be the ones doing that. Whether it's handing over a piece of paper, whether it's have a short two or three minute conversation with the beneficiary, but also we've heard from those people, that they are the ones that filter information from CMS or from the Medicare contractors, and then talk to you; that they're the ones that sort of have to pay attention to administrative issues and bring to your attention those things that they think are critical for you to know in your practice. And again, I'd like to hear from you if that is your experience; if your experience is different than that, because the Medicare Program has primarily has historically been engaged in communications with providers who bill the Medicare Program, not the support staff, not the front office staff, not social workers and nurses. They are not direct Medicare providers. So we haven't historically had the relationships with their national associations, their regional associations. Medicare contractors don't send information to these people. It's been you that we have had that established relationship with. And primarily, our communications have always been directed toward what does the program cover, what are you going to be reimbursed for, what will that rate be? What payment policies and coverage policies, what services does the program provide? So this is sort of a new audience that for the last 18 months, we've been hearing this more and more, and certainly have started to work and have established working relationships with some of these associations, and these types of support staff or support staff of you the provider. But again, we need to hear more from you as to whether or not we're getting to the right people, the right associations, and if, in fact, they are critical to getting the word out to the beneficiaries.

So what I'd like to do now is to move into the part of the program that you have probably been looking forward to, and we look forward to both parts of our presentation, and that is we have some questions for you, which really are meant to prompt your feedback to us and suggestions that you have for us. So if I could sort of

throw some questions out. I think it's better to sort of throw a variety of questions out, specifically, on what we're looking for from you, that that will sort of prompt where we can take the conversation from here. Certainly, we want to know what do you pay attention to? When there's information coming out from the Medicare Program, are you paying attention to information in professional journals, in reading articles, or looking at ads? Are you paying attention to emails and list serves that you are signed up with in your professional associations? Do you pay attention to speakers and exhibit programs, and presentations at the conferences that you attend? Are you paying attention to the letters and paperwork that are sitting in your inbox on your desk and no one has an inbox that's this full? You're reading and looking and looking at every possible piece of paper that comes across your desk? Are you paying attention to the information that your practice manager is sending to you or providing to you? What are you paying attention to when it comes to information from the Medicare Program? Is it CMS or is it one of the Medicare contractors? I'm not going to mention any one in particular, but are you paying attention to that information? We need to know what you're paying attention to so that we can get our word in those channels. That's one big question. The other is what is working? What is the best way to get information to you? We do hear over and over again that MedLearn Matters articles are, people are paying attention to them, they're reading them, they like them. Is that enough? Is there something else? Are you paying attention to electronic information or is paper still the preferred way? Something specific we'd like to know about and that is, hand-held computers, PDAs, call them what you want, but are you using them? Are physicians using them? What are they using them for? Would you pay attention to information that came across your hand-held PDA that CMS has new facts today about the Medicare Prescription Drug Coverage Program? And I guess that's probably enough questions to get the Council started on input from you.

Dr. Castellanos: Thank you, Ms. Fritter and Ms. Lewis for your insightful discussion. You certainly have our interest. I think what we'd like to do now is just open it up to discussion with the Council, and I'm sure by opening it up, we'll be answering a lot of these and most of the questions that you posed. Dr. Powers?

Dr. Powers: I think the answer is all of the above. Because I know that our carriers will have meetings and office managers will attend, if it's a large practice. Doctors will attend, if it's a small practice. We do want to disseminate the information through our specialty societies and through our national organizations like the AMA. It's important to get that because you need to hit people from sort of all areas. So it's all of the above. And to let people know that there is a list serve that they can get on to get more information, I think that would

be helpful, too. I'm not sure—we may need to advance awareness of the list serves, so that some people can get on those when they don't know about them. But the answer to that is all of the above. And actually, I think I'm more concerned about how my patients are going to learn this. I have a lot of patients that are functionally illiterate. And when they call 1-800-MEDICARE about these other drug cards, they don't know what to do. It's overwhelming. It's too much for them to understand. They need someone to sit down with them, and go through things, help them fill out the applications.

Ms. Fritter: If I could comment to that, and that is to say that as I mentioned there is a, there is another component within the agency that is absolutely responsible for education and outreach to those 42 million beneficiaries. And we understand as an agency that that is critical. There is a variety of needs amongst that population and it's a huge population to reach, and there needs to be many many different activities, which we are talking about and already engaging in, in a much broader way than was done for the drug card. At least we have some experience under our belt. We've been able to expand on the grass roots approach, the associations and the types of people and places that beneficiaries go to get information about their healthcare decisions. So what we are planning to do is to also mirror with our outreach to physicians and other providers. Whenever there is some type of mailing to beneficiaries, if it just goes to a segment of beneficiaries, not to all. If there is something released to advocates and caregivers, or state health insurance counselors, we will mirror that with a MedLearn Matters article to say, Information about the formularies or information about enrollment, information about eligibility has been released today to beneficiaries. Here is what that fact sheet said. Here is what the brochure contains so that you will also have that information that was released to them in a coordinated approach.

Dr. Castellanos: Dr. Rapp?

Dr. Rapp: Well, with regard to professional journals and things. Journals are usually for scholarly articles, and perhaps you're already aware of these, but there are a lot of newspapers for different specialties. The AMA of course has AM News, that's a newspaper format. But maybe most doctors get their news from their specialty areas. Like in emergency medicine, which is mine, there's a thing called Emergency Medicine News. It's not something you pay for. But it's in a news format. That would be a perfect ve—people like to read those, because there's stuff about how to make your practice more successful or whatever, different things, and it's not scholarly, but it's what you're talking about, it's news. And so I would look for all those different specialty

newspapers and try to, and they're easy to take articles for. Just send a press release out to them, and they'll probably put it in. They're just like for other news items, but I would suggest you actively find those things and use them.

Dr. Castellanos: Dr. Urata?

Dr. Urata: In terms of pharmacies, I think my patients seem to get a lot of information from the local pharmacies, but a lot of my patients are now going to mail order pharmacies, like Merc Medco, and AARP, and so you know they just send out their prescriptions and they get a box of drugs back. But that might be a good place for [laughter]

Dr. Rapp: That sounds good.

Dr. Urata: Yeah. It comes in by dogsled, actually. And so that might be a place where you could put some stuff in and then MGMA, we send our administrator to MGMA every year. And so he can get updates. And then he gets updates from them, so that might be a source for some of the information you want to send out. Now I do get a list serve from Medicare, but I don't recall ever getting anything on this. Is there a different list serve from CMS? There's seven of them? Several. OK. So I just got to find the right one. How do I do that?

Ms. Lewis: You actually go to CMS.HHS.gov/mailinglist and then there's an entire list and you can check off the boxes of which list serves you'd like to hold onto.

Dr. Urata: So I can also eliminate some, too.

Ms. Lewis: You can eliminate, which sometimes you'll find that if you get too many—and this is something, if you're too busy to do this, this is something that your practice managers might be able to—

Dr. Urata: No, he does I think get some of that stuff and passes it through us. All right good.

Dr. Castellanos: Dr. O'Shea?

Dr. O'Shea: Some of the questions are all these Medicare beneficiaries going to be receiving this drug card? If you are a Medicare beneficiary, you can get the drug card?

Ms. Lewis: The drug card campaign is something that is out there now. We're talking about prescription drug coverage, and all beneficiaries are eligible, but it's an option program. And what's going to happen is if similar to Part B, if you waive Part B, and then later you decide you want to join it, there's penalties associated with that, financial penalties. And for some people, they may decide, I have my health insurance through my employer, I'm going to try either a Medicare Advantage Plan or a Prescription Drug Plan and stay

with regular traditional Medicare. If you leave your retiree benefit plan, and then you decide this isn't as good of a deal as I had when I had my retirement benefits, in a lot of cases it's too late. You can never go back. So it's complicated decisions for beneficiaries. It's a lot to think about. And I know in my own case, just thinking about my own grandmother, my own great aunts, and I think about them having to face this. If they got something from Medicare, about this, they wouldn't understand it, and so that's part of the challenge. That's part of the problem that we're facing as an agency. Is to how do we reach these beneficiaries that can fall through the cracks. And I don't know if you're familiar with the state health insurance assistance programs in your state? Are you all familiar with that program? Every state has a SHIAP, a state health insurance assistance program. Where they have counselors that would, actually I sent my mother-in-law to a SHIAP to sit down with her and say OK, Mrs. Lewis, this is where you are now. These are all the possible options that you have, and this person who is very motivated, most of them are volunteers, were training men, the agency is training these SHIAP counselors and they will sit down with your patients who may need that care; who may need somebody to sit down with them. So this is another resource, and what we want to do it let you know as practicing physicians all of these are resources that are available to you. And there's a lot. And we recognize it's hard for you to keep track of this, but that's another option. But I must say that SHIAP counselors really reach a very small number of Medicare beneficiaries and so that again, is an issue.

Dr. O'Shea: And then there are some financial tiering of the benefit. My comment would be when they first sign on, please have some type of a knowledge base that they have to have before they can sign on. And I don't know how to do that, but what you're trying to do is alleviate a lot more hassles for them, make sure that this is the proper thing for them to do. Like an application period or something like that, where maybe there'd be a give and take back and forth to verify if this is the right thing. Also it might not sound nice, but if you put something in my waiting room that has too many details on it, they're going to think that I know everything on that pamphlet. So the one that's in my waiting room should be the one that says this is where you'd go for this. This is where SHIAP is, this is where the 800 number is, this is where the website is. Investigate for yourself and your knowledge can benefit you. And those things. Because if you put anymore more than that, then it becomes that I put that there so that they can ask me more questions on it instead of me giving me medical care.

Dr. Castellanos: In the interest of time, I'd like to just get a few more questions and then perhaps during the next 15-minute break, we can come up to you individually and give our comments. Dr. McAneny?

Dr. McAneny: Yeah, I'm one of the list serve junkies. I actually read all that stuff. But I delete what you sent out recently and the reason that I do that is that over and over again what happens is you're sending out stuff that says here's the program, and it's wonderful. And it ends up looking mostly like propaganda for it, and it doesn't end up looking like any things that are details. So what I need, rather than to be the person in the front row to say this is wonderful, go sign up, is what CMS really needs to do, I think. Is to get a computer program, and maybe you need to hire the Google people, who can search things well, and you need to have a program where Medicare beneficiaries can enter in their drugs, and it can search all the programs, and it can come up with the ones that have their drugs on it, and it can list the prices that they get for that. Because that's the information they really need to be able to make a logical choice. They don't need another pamphlet to call and say, this is a wonderful program, and you guys all should join up. They've heard that and they don't believe. We do, in my practice, was funded through the drug benefit money, but I don't know whether it'll be funded at all now, a pharmacy tech, who does nothing but help people get their meds. Explain their prescriptions, help them get chemo, help them get non-chemo drugs, and what happens on the front line is that we really don't want to pay our nurses and folks to do this. I cannot afford to pay a chemotherapy nurse to spend time explaining this program. And I won't do that, but we did have this pharmacy tech person, whom we hired, because if I can get somebody free chemotherapy, that's worth her salary a lot. So what she ended up doing was trying to get people signed up on the right drug program, so she would go through their list of drugs and try to figure out which program covered their drugs. And then the companies would raise the price, or she would say they got three drugs and the person would take prescription to the pharmacy next week and it wouldn't be on the program. And they'd come back and they're really furious at her, and then at me. How dare you hire such an incompetent person who gave me bad advice. So what we don't need is more brochures and pamphlets and articles and stuff like that. What we need is a way to search all of these things. Have it come out with a thing that says Products A, B, and C will cover yours and these are to pay the amounts that you will pay for, so that patients can actually have some sort of data to figure it out by.

Ms. Lewis: I do have to say that that does exist, actually on Medicare.gov, there is a data base where you, when you go, this is for beneficiaries, but anyone who's counseling beneficiary could do this. You need to have your list of prescriptions, the dosage, the frequency that you take it, and you input all this information into the data base, and you also say which state that you're a resident in, because in some cases, this is talking about

the drug card. That's different than coverage. So this is with the card. Sometimes your state pharmacy assistance program with a better deal for you than the drug card, which was the case for my mother-in-law. So you go in and you actually put in all the names of the prescriptions of the drugs, and then it will tell you these are the cards that have the drugs that you take in their formularies. This is how much it will cost you per month if you went with card A, how much per month card B, how much per month card C, and so there is going to be, just so you know, and maybe that was our fault for not making that known to you, that that was available.

Dr. McAneny: Is that available for the program?

Ms. Lewis: That's what they're working on. That is supposed to, and that is one thing, we really want to rely on these MedLearn Matters articles to make sure that you know these things. And again, lessons learned with the drug card. Yes, we did have that information in the information we sent out to you but like you said, do you have time to read these lengthy brochures. And our brochures just know that we do not develop the brochures for your patients. That's another area of the agency. What we do is gather all this information, disseminate it to you to let you know what is out there. But we do know the people that write those brochures and we are happy to let them know your comments. And they are happy to hear your comments. So there is going to be another comparison data base that's being developed for the drug coverage.

Dr. Castellanos: Dr. Senagore?

Dr. Senagore: You've done a great job of trying to educate the provider population, but I would submit that the goal of the whole program would be to take the providers out of the loop. Because this is really a beneficiary knowledge base that needs to be acquired. And if anything, you could say that I would be biasing a selection, potentially, for the beneficiary. So the more they can come in and make their own decisions, based on what's available to them and what may be the best choice for their individual situation, much like you can flip through any of the magazines, and you know, figure out your retirement program. And they have all those little quick answers, things where you can fill in the blanks, and it leads you to some solutions. The more you can make that kind of thing accessible, and maybe simplify it for the providers to have a wall poster that you can put in your office and say if you have a question, this is the email, this is the phone number, this is the address, so that they can access you folks directly. That might be the most advantageous for the providers.

Dr. Castellanos: I want to emphasize that point. That the physician services that we provide in our office would be an uncovered service. And I don't know if you know, but there's a push by the pharmacists now,

to get paid for educating and discussing this with their patients. I talked to Robin earlier, last week, and I have a 9-man practice, I have four offices. I have a surgical center, and I have a lab and X-ray. One Monday, we counted the number of phone calls we made and the number of phone calls we got, that includes to the pharmacy to the hospital to the insurance company, that number, she guessed about 70. That number exceeded 3,000. I hire six people now just to answer the phone. Now, I could afford that when I got paid under AWP and I had some excess money in the pot. I can't afford that anymore. So anything that you can educate the beneficiary and take that burden away from us, is going to help us tremendously. And you know AARP is an excellent organization, and I think you need to go to them. But the important thing here is that in an ideal world, it would be nice for me to be able to sit down and discuss this at length with my patients. But I don't have a boutique practice. I don't have a concierge practice. I have a practice that provides service. And unfortunately, my patients are going to be looking at me to provide this, and this is going to be an unfunded mandate again. I know we'll have one more point, and then who would like to give the last point? Dr. Powers.

Dr. Powers: I just have a question. Because certain national groups are going to want to disseminate some of this information so that doctors will be able to answer some of the questions, or at least be able to tell their patients where to go, I know my patients are going to ask me. And then I'll just say, now I'll know where to tell them to go. But just for the articles, can they directly contact you for information?

Ms. Lewis: The beneficiary?

Dr. Powers: No, the national organizations?

Ms. Lewis: Oh yes, and please know that we do have very close working relationships with many of the national associations and so we are in constant contact with them. And a lot of them are based here in Washington, D.C. and we meet with them in person and again, most of the information that we send is electronic, to push out to their membership. So really pay attention to what your association sends you.

Ms. Fritter: But if you want to make sure that your association, you have in mind, is in contact and has a relationship with us, they may certainly may contact either one of us, and we'll be sure to facilitate that, yes.

Ms. Lewis: And our contact information is on the last slide. So please don't think that just because this session ends that you don't have any other avenue to get to us. We really welcome you to think about this more and send us your suggestions. Let us know which associations you belong to. Maybe one of the associations you belong to isn't in our directory yet, and we can make those contacts. We really appreciate your help on that.

Dr. Castellanos: Well, we do want to thank you for this insightful discussion and we appreciate it and I'm sure you're going to have a lot more feedback.

Ms. Lewis: We appreciate that, too, and we suggest that the Council consider having someone from the other side of CMS come to talk to you on beneficiary education. Again, we're happy to take this information back to our colleagues, but it may be interesting for you to understand how materials are developed for beneficiaries and how they're disseminated because I think that your feedback would be very valuable to those colleagues and the beneficiary choices area.

Dr. Castellanos: Thank you. Now we've already had the break before their talk, so we're going to keep going. Our last presentation for the day is probably one of the most important presentations we'll have, and that Pay for Performance Initiatives. Dr. Trent Haywood is an internist. Lives in Chicago, and when he's there on weekends, he still works in the emergency rooms. So he's in the trenches like the rest of us. He certainly understands the practicing physician's point of view. Dr. Trent Haywood is the Acting Deputy Chief Medical Officer, of Clinical Standards and Quality. And he's put together a real comprehensive document on strategies for today for superior health care for tomorrow. He's excited about this and we are too, and we're looking forward to his presentation.

Pay for Performance Initiatives

Dr. Hayward: Thank you, Dr. Castellanos. Thank you to the members of the Practicing Physicians Advisory Council. What I would like to try to do today is provide the Council members with a little context and understanding of the issues that we're trying to address through actual Pay for Performance Initiative, and then would encourage your active participation and feedback as we continue to move forward, how you actually see us doing this in a way that's positive and constructive for all of us. So let me begin.

This is just a brief overview of quality and definitions of quality that we currently see in the marketplace today. One of these two are offering the definition that many of us will use when we try to define quality for the sake of external stakeholders. We're really trying to understand what is being meant when we're talking about actually paying for performance or paying for quality. At the top, you see the Institute of Medicine's definition, the degree to which healthcare services for individual population actually increase the likelihood or desire to help the out [cause?] and are consistent with current, professional knowledge. And then at the bottom of the slide what you see is the Agency for Healthcare Research and Quality, what I consider to be

more of a social utility approach to quality where you're looking at doing the right thing, at the right time, in the right way for the right person and having the best possible results.

This I just wanted to quickly give a tribute to, kind of the father or godfather of quality measurement, is Dr. Codman. And this is the past environment in which he was acting. This is circa 1910 in which he was at the time still at Massachusetts General Hospital where he, I mentioned that, perhaps the results as a whole would not be good enough to impress the public very favorably, second is it is difficult, time-consuming, and troublesome, and third neither trustees of hospitals nor the public are as yet willing to pay for this kind of work. Some would say that we may still be in that same environment, but I'm going to provide evidence to the contrary as to that.

Here are three at least issues that I would definitely encourage your feedback as we move to the question and answering session. But let me just briefly state, these are at least on the quality problem side, these are three areas in which we continue to work now. Number one is the lack of meeting expectations for American healthcare community at large. And I mean that from the standpoint of both a practicing clinician as well as kind of a public policy person, that we are not quite at the level of expectation I think we would all want as participants in the American healthcare community and I have further slides to illustrate that point. Second, previously there had been incomplete assessment of performance across the board. I think we're making great strides to actually be able to show a more complete picture of that assessment of performance but that will continually evolve equally over time and I welcome your feedback. And then thirdly, the incomplete infrastructure to support ideal provision of healthcare quality. And that's the reason you see more and more push from the department as well as from the Centers for Medicare and Medicaid Services are really trying to improve opportunities to actually get their proper infrastructure in place in physicians' offices or hospitals to actually allow for that quality jump that we want.

This one I call big quality problem, but it's really kind of should be retitled the Chicken and Egg Scenario when it comes to quality. A lot of times depend upon where you go and have the conversation on Pay for Performance or even on quality improvement in and of itself, the question becomes whether or not there's an ROI, or return on investment for the quality activities that's underway at least as the current healthcare financial structure is situated. And so the question has always been, whether or not that in and of itself to me, whether it's the chicken and the egg in the sense of does that illustrate the fact that we actually need to change the marketplace, meaning change the current financial structure, or does it actually lead others to conclude that we

can't actually improve on quality until we actually have that financial incentive? Or another way of putting it is in and of itself, if you know that you're stating to me that there's little return on investment, it seems to speak to itself that we have an inefficient marketplace in comparison to other markets that actually reward higher performance.

This is in your handouts, I believe, because you probably can't see well from up there. But this addresses kind of the first prong on that quality problem that I had mentioned as far as lack of achievement, kind of the success that we would want across the American healthcare community. And what this is is a reflection of the World Health Organization's ranking of countries and the level of quality that they provide. And if you actually look at the arrows. They are the United States of America. And if you look at the third column from the right, what you see is that we're the number one when it comes to healthcare expenditures, but if you look at the absolutely last column to the right, we're ranked 37th by the World Health Organization, and we far exceed a lot of people as far as their expenditures. So we're definitely spending the money as far as the overall healthcare expenditure, the 1.7 trillion, or 15% of the GDP, but it doesn't necessarily correlate with the actual quality outcomes that we would want.

Unidentified speaker: Who's number one, Trent?

Dr. Haywood: I need to pull the list and see who they actually ranked as number one. Being American, I'm a little self-centered. But I probably should have looked. This is also to highlight I think the background some more, about the milieu in the background in which all this activity is underway. I think all of us have become quite familiar if not all familiar with the Institute of Medicine landmark reports on To Err is Human and the concerns around patient safety and the need to actually encourage the changes the system that would actually allow us to address our patient safety issues as well as crossing the quality chasm, where the Institute of Medicine laid out six aims that we should all be striving to achieve around the notions of safety, timeliness, around effectiveness, around equality, efficiency, and patient [?], and so those six aims. And then finally, listing some of the priority areas in which we can all start to move forward.

This again, I would refer you to your own handouts because it is difficult to see here. I shown you before on the World Health Organization kind of at a macro level at how we rank in comparison to other countries and then this is an article that is off-sighted by Beth McGlynn and her colleagues at Rand. Actually they looked at a total of 439 indicators, but what you will see across the board, as you look at the right hand

columns, just going down, that roughly on average, we're talking about recommended cure, being provided 54-55% of the time. And it's across the board whether it be preventive services, as you see, acute and chronic services, or whether you break it down as to screening, diagnostic treatment and follow-up as well as all ranks right around that same area. Now as recently as last week, I was at a conference in which they actually juxtaposed this slide with Shaquille O'Neill's shooting free throws, saying we're doing about the same, and that's a little scary if any of you ever watched Shaquille shoot free throws [laughter] But that's the kind of state of the situation, overall across the board, that's where we are. And then to drill it home further, we were actually able to take it from a patient standpoint and say if you have a particular chronic condition whether or not you've actually received all of the recommended care, the numbers would actually be lower, because that would require you to actually receive everything that you were supposed to receive before you get a positive result.

This is just a highlight, the work that we've been doing from the Quality Improvement Organization standpoint. This is also kind of the impetus for a lot of activity that occurred even prior to Beth McGlynn's article, this Steve Jencks one our colleagues did, looking at changes in the quality of health care at the state level and plays into next slide that I will show you. But what he did was basically take 24 of our quality measures that we have been working closely with—state hospitals, primarily at the state hospital level—and trying to show some improvements, and then looked across the board at those 24 measures and were able to come up with a ranking as to how well different states did across those measures.

This is an article I just quickly mentioned that if you actually to have time to talk about this more fully, what it actually talks about is not only the quality from the standpoint of whether or not we're achieving what we should achieve, but also it incorporates the notion of how much the cost of poor quality is in the system, so the cost of poor quality, so whether that be, in this situation increased length of stay, secondary to complications or increased morbidial mortality, and the impact that poor quality has on our overall financing of healthcare. So that I told you is a brief snapshot. But one of the big issues that we have when we talk about Pay for Performance is really trying to get at the angle of quality. Here's another example of somewhat of a payment issue, although it is directly related to quality and particularly if you look at that second bullet, which is 5% of the enrollees consume 47% of the dollars. So you have a disproportionate number of enrollees that actually impacting the way that we actually finance our healthcare structure. And then you have this other half that really doesn't bother us at all in a way of actually purchasing or trying to provide services because they only consume 2% of the dollars. This is

one of the disconnects as well, when you talk about actually how you pay for performance, or improve performance, that you have a disproportionate number of enrollees involved with the healthcare dollars.

This one again, I would ask you if you can't see that well, I would ask you to look at your handouts in your book. What we did here was one of the colleagues in my shop actually ran some of the 2001 data. And this is only Part A data, so it doesn't take into consideration Part B data, and this is looking at ambulatory sensitive conditions or the Agency for Healthcare Research Quality, ARQ's prevention quality indicators. Now there's literature to suggest that maybe 30% of these admissions are preventable or can be prevented. But we looked at these numbers and you see, just in 2001 at the bottom of the total column for that first column, these had in excess of $12 billion that were spent on these particular conditions. So even if we took 5% savings, and we were very conservative, and said 5 – 10% savings, you're talking on the order of $638 million to $1.2 billion that could be redistributed in our system, currently, if we were able to even prevent one in twenty admissions or one in ten admissions for some of these conditions, which I think if you look at some of the lists, whether it be COPD or urinary tract infection, dehydration, even hypertension, where you're looking at hypertension and then finally of course with diabetes, long-term and short-term complications. We really do have opportunities in which we can actually improve not only the quality of the services that we provide, but actually allow for some redistribution of some of the expenditures that are currently in the system.

And then I think all of us have become quite familiar, if not already familiar with some of the work that Jack Wennberg and colleagues at Dartmouth have done, and drilling down a little bit more, talking about kind of variation problems. What this slide represents, red is pretty intensive in service and cost of services, in particular geographic locales in comparison to others and I let all the members of the PPAC Council look at their own individual regions and see whether they're red or not, but what it is designed to do is show that there's intensity levels of service and dollars associated in these particular reasons that don't actually correlate with quality. So it's not actually to say the expenditure reflect high levels of improvement of outcome at all.

This one again, if you could look in your handouts, because it shows you more and this follows right along with that last, that Dartmouth-Atlas variation. What the officers were actually able to show according to their literature is actually a negative trend in the sense of spending as it relates to how well outcomes have occurred, and this again, is at the state level. So using both the Steve Jencks article that I talked about, as far as how we actually measure the quality of the services at the state level, and taking into consideration some of the

Dartmouth-Atlas information to do some risk adjustment, and what you see at minimum, whether you agree or disagree with the line as far as whether there's negative spending, what you can definitely conclude is that there's no correlation between the expenditures that are incurred and the level of quality or the quality ranking at the state level.

So this quote is often sited, Winston Churchill quote, I threw in because the notion that you can always count on Americans to do the right thing after they've tried everything else. And I think we've definitely tried multiple different ways of getting at this issue from a volume perspective and tried different opportunities to be able to do that, but now I think we're coming up to the place where we really are trying to look at ways to do this by linking it to quality and really are trying to improve performance out there both for the individual practitioners, whether it be from infrastructure support, but also from the underlying [?] from the patient perspective to really allow this to occur. So that's where we currently are, and that's the current environment.

Now this was MedPac last year, and as you know as of last week, they came out with new recommendations. So the current environment last year, where they were actually looking at growth and volume of physician services, and I assume that Steve Phillips or Ken Simon and some others probably have already briefed you on kind of where we are, where we're headed as far as those activities, in the global sense of where Medicare dollars in the healthcare environment is. Just briefly, MedPac did last week make recommendations that Medicare really should look forward to moving forward on Pay for Performance initiatives for physician services, for hospitals, and for home health agencies.

Also, of note, we've had a lot of opportunity and this is just one example of where the National Committee for Quality Assurance or NCQA, and American Board of Internal Medicine have come together to really try to align some of the activities around board certification and quality improvement and similarly a lot have come to CMS as well to see whether or not we can do that on a much broader perspective. So in other words, not only are you looking at the quality measures from your own internal quality improvement perspective, or maybe even looking at them from Pay for Performance perspective, but also that is coordinated with your overall board certification or continued medical education process, so that there is not a disconnect that we're actually all moving together collectively.

And then this is only to highlight a few of the multiple activities that are out there in external environment as it relates to Pay for Performance. And so this slide just quickly highlights three of the ones that

are large because they're at the statewide level, comparison to some of the other programs. So you have California, with the integrated health care association that has a statewide with six health plans involved with this particular one to the left. You have Massachusetts heavily involved at the state level also, looking at Pay for Performance at the state level. And then more recently, Minnesota has also come forward with their governor, really the Buyers Health Care Action Group looking at trying to improve state quality improvement and Pay for Performance at the state level.

This was an article that was penned in Healthcare Affairs that actually had put the challenge to CMS and you see some of the noted signatures there, saying really if we're going to move forward, meaning the collective we, we really need the government to be not only involved, but they were suggesting that Medicare should actually take the lead, particularly as a way to actually being able to look at the Medicare data, being able to work with providers, given that we have the technical assistance through the quality improvement organizations and really allow us to kind of use our platform to work with external stakeholders so that there isn't this disconnect between what the public is doing and what the private sector is doing. And so this article was pushing for Medicare to really try to move forward in the Pay for Performance arena.

I want to quickly highlight sections here, for the remainder of this PowerPoint presentation, unless specified otherwise, section refers to the Medicare Modernization Act, so the new Medicare law. Just want to quickly highlight as I started out earlier talking about inroads in the Institute of Medicine had done. There is a report that Congress authorized us to work with Institute of Medicine on, to really allow us to look at ways in which we can work with interactional Fee for Service program as it's currently constructed and come up with policies and encourage decisions that will allow us to really start moving forward on improving or enhancing rewards for those that are performing well. And so we anticipate that we will have a draft report in June, but a Final Report will come from the Institute of Medicine probably around Thanksgiving time of this year.

You can't see this well, so I would ask you to look at your handout in this backdrop, in this color. What I want to quickly remind you is that although this talk is about Pay for Performance, there's multiple layers that we use within the agency to actually try to improve quality, and some of the other ones that I've mentioned already were the Quality Improvement Organization under technical assistance. The consumer websites that we've had available, whether it be the nursing home consumer website or the home health consumer website, and later this month, or on April 1st, we'll actually launch the hospital compare website, where we'll have

hospital information available as well. And then we'll continue to do our other activities as well, particularly with the regulatory agencies where we continue to look for ways of assist and provide with standards of conditions of participation and the like.

Now, in order to do this effectively, or as well as I think we would all want to do it, there are several issues that continue to come up as I have this conversation, whether it be with large national organization or whether when I'm going out and talking on a more local level. One of the issues off the bat is trust and credibility. Trust and credibility, both in the terms of the standpoint of the relationship between physician and the government, but also trust and credibility as it relates to underlying measurement. And the way that we've approached that is through a consensus process and primarily we work with external stakeholders and the National Quality Forum that has a consensus development process, and we actually get the measurement of development activity at least the consensus or endorsement of it takes place at the National Quality Forum so that everyone understands that the measures have actually been endorsed and then similarly, as far as the actual use of the measurement activity, there continues to be a lot of work that we continue to work with external stakeholders establishing the trust as needed to actually appropriately use the measures in the way that we had anticipated. And then we're visiting constantly, asking external stakeholders to let us know and we continue to work with them to make certain there's not any unintended consequences for the use of those particular measures, or they weren't actually [?] incentives and that's particularly the case if you're talking about outcome measures and why we would need risk adjustment for such outcome measures.

The benefits on the flip side, or the benefits we anticipate relies for both physician as well as providers is that it does actually start, particularly with second bullet point. It really starts to align the financial model to the actual professional goals of improving the quality. So traditionally, when I said that we tried various ways to look at it from a volume perspective, trying to look at it from cost perspective, this really does allow some alignment of the financial model where we're aligning actually our professional goals are far as improving quality and providing the best services available with the actual infrastructure that we have in place as far as trying to support that activity. And so that's, at least the first bullet as far as rewards [?] has been encouraging overall improvement across all the centers. And then I've already articulated the third bullet.

Now just to quickly, this is at a high level to get you a quick snapshot of some of the things that we consider when we talk about paying for performance, and continues to be some of the [?] or concerns that we

always spend time talking with the external stakeholders is how do you get the data? Where does it come from? And how are you going to be able to collect that type of data? And what the impact that it would be at the individual practitioner level as far as trying to collect that data. And then the second bullet point relates to actually the dissemination of that information, meaning what information is being provided to us, would be CMS or to external parties and how is that information going to be used, whether or not it's going to be used for public reporting, or is it going to be disseminated to other avenues. And then finally, the financial rewards, which I'll talk a little bit more about in some subsequent slides as to how you actually package it.

So this just gives you a brief, again, at a high level, different ways in which different Pay for Performance Programs, whether it CMS or whether it be the private sector, try to reward quality. And so the first bullet talks about relative quality. And what I mean by relative quality is that you can actually reward performance based upon how well you do in comparison to a specified peer group, if you will. So if you're in a Pay for Performance Program, and I'll give you one example of relative quality and then give you another example of absolute threshold. So I premiere a hospital quality incentive demonstration that I talk about a little bit gives you an example of relative quality. The second one is absolute threshold, so in other words you set up front kind of a benchmark as to what you think the goals are going to be for that particular program, and not necessarily worry about it relative to peers and so to the extent that practitioners or providers meet those particular benchmarks, then they would actually be available for additional bonuses for the Pay for Performance program. And then the third bullet I want to highlight particularly for this group as we continue to have more dialog around Pay for Performance is this bullet on improvement. MedPac recommendation had encouraged us to also look at linking payment to quality improvement, and there's external stakeholders that really believe this may be where the biggest bang for your buck is. And what they're articulating there is that instead of not only rewarding people that are really performing kind of at the high end of the spectrum, what you really want to do is get the biggest bang for your buck. You want to encourage those who are maybe at the other end of the spectrum to really come up to what would be the average, and that would actually allow for both improvements in quality, but also improvements in terms of efficiency of those resources that are used. So some will continue to argue that improvement relative, improvement may be the benchmark that you want to look at. And then I quickly highlight under the second large bullet is financing of the incentives. How we actually do it—and there's three different models, at least three different models that we talk about as far as how you actually create the pool.

And one is across the board reduction where you create a pool from the money that you already had currently available and then the other two are off-setting penalties, or off-setting segments which I'll highlight and actually two of the demonstrations that I'm going to provide more specific examples of.

The next two slides are just a quick listing of, and it's not, I think it's not the entire spectrum of activities that we have underway, but it does give you some sense of the activity that's currently underway. So this is a list of some of the activities that we have underway that relates to either quality improvement or particularly as it relates to Pay for Performance. I believe this second slide also highlights some more of those activities.

Let me quickly try to give you two examples of how we've done Pay for Performance up to date. There are only two examples and by all means, they're not intended to be the final or despositive as to how CMS is actually going to move forward, but it does a lot for some inside as to how the activities have taken place up to this point.

So the Hospital Quality Incentive Demonstration, or Premier demonstration was a demonstration that came about where the Premier organization was able to come to us and inform us that they actually had hospitals that had already been working in a collaborative spirit on knowledge transferring information as to how it relates to how you can actually improve quality through the Premier perspective system. And we were able to actually provide information beyond kind of the ten measures on the hospital side that we already had going on with the voluntary reporting initiative. And so what you have is 34 measures, it's actually 277 hospitals that are participating in this demonstration about five key areas. And there are heart attacks, acute MI, heart failure, pneumonia, CABG surgery, and hip and knee replacement.

This is just a quick, and you'll see this in your handout, the next two slides give you examples of kind of the source of quality indicators and how we actually were able to come over to 34 measures that applied the Premier demonstration. I can come back to that if we need specifics on that.

And then this just quickly highlights that in addition to what we've done as it relates to both the [team mission?] on the hospital supporting side as well as some of the activity that was listed previously from a process standpoint that Premier also demonstration does have an outcome measure that's part of it.

This tells you briefly how this actual recognition and financial reward program is structured, and then I'll give you actually the schematic that makes it simpler. But basically, out of the top 50% of the hospitals that

are participating, so out of the 278 the top 50% will actually have their data released on the CMS website, publicly available. And then those that are qualifying to the top two deciles there will actually be bonus payments according to those 5 DRGs that I've discussed, with the top decile receiving a 2% bonus, and then the second decile receiving a 1% bonus for that DRG.

I think this picture is kind of more worth the thousand words that are on the other slides. And so what this actually does is say condition X, and as I indicated, there's 5 DRGs that we're talking about, and in the base line that we set here. We set a baseline based upon the historical data that we had available. And then as we continued to move forward in the years, it's a three-year demonstration, those that are in the first and second decile will actually be in the money in the sense of actually getting additional bonus payments for those particular DRGs, and so as I indicated, the first decile will get a 2% bonus for that DRG, and the second decile will get a 1% bonus for the DRG. That red line and as you move out in the third year, and you see in anticipation of that, those will continue to improve. And actually some of the preliminary data that we actually have actually shows that we're already seeing significant improvement just with three quarters worth of data, without even financial payments that have been dispersed as of yet, but we've already seen movement beyond what we anticipated just with this diagram. And so what we anticipate is that there's likely opportunity that there will be anybody below this payment adjustment threshold, but what that payment adjustment threshold represents is the off-settings that I had mentioned on the previous slides, where how do you pay for it? And the thinking under this particular demonstration was that to the extent that any institution, part of the demonstration that were below the bottom two deciles at the end of the three-year period, then there would be off-setting penalties for those particular institutions. The thinking around that to the extent that there isn't, and the demonstration has been successful in the sense of actually improving quality and we're anticipating by improving quality and paying for that bonus, that there's reduction in morbidity and mortality and high complications and readmissions, and so that there's already cost savings that are part of the actual quality improvement strategy.

This just re-highlights kind of what we had talked about, some of the goals that we anticipate and how we actually anticipate that there would be benefits, both from the quality standpoint as well as the financial standpoint. Then I want to quickly highlight the Physician Group Practice Demonstration that's also been announced this year, and although this is part of previous legislation, 2000 legislation, this is centered particularly on large physician group practices because we knew that there were going to be some infrastructure

issues but we wanted to go ahead and move forward and test the model, and so for this particular time, this is 2000 when this was designed. We designed this in 2000, looking at large physician group practices that have multi-specialty groups, with well-developed clinical and management information systems designed. And there's primarily designed really to encourage coordination of Part A and Part B service and promote efficiencies as is indicated, as well as improving outcomes.

So the way this one is designed is that there's also bonuses. And this one takes into consideration for physicians, I think all of you can understand, is a situation where the current structure, the current financial structure doesn't make it as easy, if not perverse in centers to [?] to actually do all the patient education coordination. For instance, if you have a heart failure patient and you really are trying to do the best thing to keep them in their own particular community, and their own environment. Whether or not there's actually reimbursement for any of that activity that you or your staff actually spends time on, irrespective of the rewards for the overall kind of Medicare [trust line?], and so what this says is recognizing that there are physician practices that are already out there doing this activity, how can we actually support them and reward them in that effort. And so what this was designed to do is to actually be able to get at that, allowing physicians to be able to provide such services to the extent that they wish to of their volition, in the way that they choose to do it, with the caveat being that to the extent possible that if there was cost [setting?] that we would share in the wealth. And so what we have here is a 2% savings threshold, if physician practices, and this again is a three-year demonstration, if physician practices are able to demonstrate that there's actual savings beyond the 2% savings, then there's opportunity for them to receive bonus payments. Now keeping in mind the way this one is structured, the physicians are not at risk in the sense that they continue to bill Medicare as they traditionally billed Medicare under a Fee for Service Program, so even though they are participating in a demonstration, they continue to bill Medicare as they traditionally would do as far as Fee for Service and then to the extent that at the end of the demonstration period, that there are savings thresholds, then there would be these bonuses. And the first year, what you see under the bullet—the first year, the savings and quality are broken out 70-30. And what that means is 70% of those dollars would automatically go to the physician group practices for the savings that are incurred. And then there's a 30% quality matches and the design of that was intentionally to make certain that there wasn't any preserving savings in the sense of decrease in access, really focus on savings to the

detriment of what we want as far as overall goal of improving quality for the beneficiary. And then that fourth bullet highlights that there's a 15% maximum as far as a limit on the bullet.

These are just a few more that I highlighted, that there's other activities underway. There's activities under ESRD as well, looking at disease management demonstration. And I take a moment to highlight Section 649 because you're going to hear more about that in the short term within the next two months probably. What this one says in comparison to the physician group practice, is looking at small to medium sized physician, recognizing that for the physician group practice we weren't able to do this. And particularly, what we wanted to do is highlight the fact that we really want to try to improve that system of care, that infrastructure that's in place and trying to promote the diestrum of information technology to not only allow for decision support, but also improve the overall infrastructure in the standpoint of being able to disseminate information timely, and get provider feedback and being able to provide that information back to them for their own quality improvement purposes.

Last thing on 649 because I talk about 646, we do anticipate that's going to come out later this year, is in four states is piggy-backed upon the Doctors' Office Quality Improvement Project, or DOQIT project, California, Utah, Arizona, Massachusetts, I believe are the four states. I need to verify it. But those four states are the states in which that section 649 is anticipated to go forward.

Section 646 I wanted to just highlight. We're anticipating that there's going to be a request for information probably later this year, hopefully within the next couple of months, but we're definitely hoping by summer that we'll have this information out. This is different than the others in that this one is not necessarily predicated, or if you will, built upon the Fee for Service Program in and of itself. But really is designed to actually allow for some of the conversations that have continued to occur as to what is the best way, are we really going to restructure, or to really go at looking at how we can improve quality and efficiency without out necessarily have to string to attach to the necessary current Fee for Service Program. How will we go about doing that activity? And so I think it would be interesting for all of you, if you would, to take a look, you can get this information, all of this, on CMS.gov website, around Section 646. There's also I saw an article that Jack Wennberg had in here about these activities as well as others that have an interest in this. So this is going to be one of those areas I think that's definitely going to have more and more interest on Section 646.

And then Chronic Care Improvement Program, unlike the other activities that I've primarily talked about thus far, this is not a demonstration. And I should say, when I mean a demonstration, what that traditionally means at least from the CMS standpoint is that we normally get a waiver from the traditional Social Security Act as how we normally pay under the Social Security Act. So any demonstration, what we're talking about is that we've gotten a waiver of authority, so that we can go ahead and make alternative payment arrangement. What this did, under Medicare Modernization Act is allow us to actually do this as part of the traditional Medicare Fee for Service Program. We have authority up to approximately 300,000 beneficiaries under this phase one. We anticipate right now that there are probably going to be 180,000 beneficiaries. And what you may already be familiar with, from a lot of literature around disease management or case management is that there has been different interventions that have shown to have some successes, but there's been limited number of population within those actual disease management or case management activities. And what this allows for, not only for CMS, but I think for the community at large that's been really active in this area, is to be able to have a robust sample to really be able to tease out which interventions are actually showing to be of benefit. So phase one allows us to do that so randomized control trial in which we will actually be able to test different methodologies of intervention for some chronic conditions. And then in phase two, based upon what we determine, under phase one—and phase one, the shortest time period is two years, but we have up to three years to actually complete phase one—then under phase two, based upon what we have there, we will actually be able to import that into the traditional Fee for Service Program in the sense of making it more nationally available. [Section 721]

So just to somewhat conclude and open up for much more dialog, I think without a doubt, if you look at kind of where we've been, in the current context, I just gave you a brief overview of the current climate out there, but there's definitely seem to be more and more conversions around both quality and cost concerns and how we can actually come together collectively, both from the provider and physicians standpoint, as well as kind of from the purchasers standpoint, and all the intermediaries in between as to how we actually can redesign a system that works toward our overall goals. And B just highlights the fact that time is of the essence, and I think most people recognize that not to act is not an option, so the question becomes how do we actually act in a way that's beneficial for all of us and that puts us in the best position to try to achieve the goals that we are trying to achieve collectively.

And then I just threw this in, because since I'm a bureaucrat, and since it had a nice quote, I figured I definitely wanted to include this. But what this highlights is the fact that I just articulated that we are moving beyond the time for which the status quo is actually defendable, and that we really are looking for ways that we can act in a way that's recognizing some of the bearings on limitations that are out there in the marketplace, but how can we actually bring everyone together and still try to move forward in a positive direction. So I believe that's my last slide, other than my contact information.

Dr. Castellanos: Well Dr. Haywood, we certainly appreciate your very thorough discussion. You've certainly presented us with a lot of interesting discussion points to include incentive demonstrations, quality indicators, and recognition and financial rewards. Does the Council have any questions they want to present to Dr. Haywood at this time? Dr. Powers?

Dr. Powers: That was quick. And I'm trying to understand something, and I'm not. I think we're buying into this because we know it's coming and we're trying to make the best of it, but I don't know if you're familiar with this article from the New Yorker on the Bell Curve, and it's actually a positive article toward quality improvement, and I appreciate that. But one of the things that struck me is because there will be financial incentives, for being number one, and being able to say you're number one, I'm only hoping that either you'll structure this so that it will be, the quality indicators will be that you've gone through certain processes and not necessarily the outcome, because in this particular article, the reason that someone was number one was partially, not really their fault, but they weren't sharing their ideas with everyone else. And that their outcomes were better and they weren't sharing how their outcomes were better. And so that's why it would be better to measure the process of what you're doing and not necessarily the outcome.

Dr. Haywood: To the extent that you raise that, there's multiple issues underneath that, so on the issue of process versus outcome, I think you'd probably be familiar, there's a lot of discussion about what is the right one. And we've always said we think it's both. And we think that you definitely want process measures, and particularly the benefit of the process measure you articulate some of those, and then the current financial structure I think makes it easier for process because that's the way we traditionally pay people is based upon some of their process. Others are deficit but our goal is towards getting some evidence of some outcome. Now the process measures that we normally collect are always related to outcomes and showing to be beneficial as it relates to outcomes, but I agree that to the extent possible we definitely want to try to encourage both the use of

the process as well as the outcome. To your starting point as the issue of whether or not we're only incentivizing whoever ends up being number one, that was the reason why I think you saw me spend some time talking about the improvement model as some have suggested, that's the way to go to show a way in which you're not only rewarding the best person per se, or the best provider, but you're actually encouraging the whole marketplace to move forward collectively instead of leaving some behind. So we're definitely sensitive to that, and we're open to more and more suggestions on how we can do that actively, particularly from the individual practitioner level. So I appreciate those comments.

Dr. Castellanos: Dr. Grimm, you've had some experience in this line.

Dr. Grimm: There's so much here we could go on probably about two hours in terms of all the issues that are going to be involved in this. And just for background, those who know, I have a quality assurance business already [?] brachytherapy with [?] implemented already on a voluntary basis have over 300 physicians and now I'm 82 centers involved and it's self-financed, and also by industry it's financing it. So I think in terms of when you're in a business, we all know is that you have to pay your bills at the end of the month. And so you have to have processes in place that actually work and actually have some meaning. And I would disagree with you in saying that you don't want outcomes. You absolutely have to have outcomes as the bottom line, because you don't care how people get there. You care if they get there. And to me that's the most important thing I've learned. And I'd like to share just a few things that I've learned the hard way and in a practical day to day operation of the business related quality assurance. Number one, all the personnel have to be involved in the outcomes and that includes the nurses, your staff, everybody. It can't be just the physicians. So everybody has to understand the outcome clearly. If they do, then they can all work towards it, and they have a stake in it. Because they all can get rewarded by it. I think you have to have objectively based standards and processes. I don't disagree that some of these things have to have processes and you can't establish the outcome. And they have to be agreed by the medical community. I agree with you completely on that. And I think the one thing that I didn't hear about is how you verify this data. The one thing I learned very quickly is if you give your report card, the person who's getting the report on, guess what? Your statement's saying they all improved, and the last three quarters, I would say go back and look and see how they reported their data. Because usually what happens is you change your own report card, and so you have to have third party verification of data in order to have anything meaningful. Otherwise it's the same old problem of any kind of studies.

I think in order to change behavior in personnel and physicians, you have to have immediate feedback. It can't be feedback that's a year later, two years later. It simply won't be implemented. People will polish their shoes, make themselves look good so they can get their bonus or whatever it is, and then they'll go right back to where they were. So just like your kids, you got to hit them right them right then, when they acting—and I think incentive based issues are also incredibly important. I think we have to have an incentive system which doesn't, that is not budget neutral. It has to be a positive reinforcement system, not a negative, punitive kind of system. I think if you have a punitive system in there, it's going to be very difficult to implement, because people will resist you right and left. That's all. I'm going to stop there because I could go on each one of these topics for hours. But I'll leave it at that.

Dr. Castellanos: Dr. Senagore?

Dr. Haywood: Let me just quickly highlight that. We, although I'm having this conversation today, and correct me if I'm wrong, we don't anticipate this will be the last time that PPAC members will have the opportunity to speak on Pay for Performance, we actually think this will be a recurrent conversation throughout the rest of this calendar year—

Mr. Kuhn: My guess is by the end of the year you're going to get to know Trent very well. He'll be back, I suspect each and every one of the meetings we're going to have a discussion.

Dr. Senagore: Just a couple comments. I think it's [impossible?] to be against something like this because [off mike] this is the way things should be practiced. But just to take some comparisons from your chart in terms of healthcare systems, you could compare the US to the UK. The death rate from breast cancer is 30% higher in the UK because there is not similar screening, and there is not similar use of [interruption] and chemotherapy. The death rate, the mortality rate from colectomy from colon cancer is twice that in the UK versus the US, so if you took those two quality measures, you would say well, how did they end up being ranked 18, and we're ranked higher? The other thing you look at the UAE, that is ranked even higher than us. There's a population with a mean age of 18 years old. The reasons for death and mortality are very different in a population with a mean age of 18 than a mean age of 45. And so you have to take those things into perspective as well, and so where the rubber will hit the road is what are the true outcome measures? What are you being benchmarked against? I mean if you use the GE approach of sick sigma, you fire the bottom ten percent every year. That's the only way you migrate the curves. There's, it's wishful thinking that you will move the whole

herd up equally. They get rid of the poor performers, because they are by definition an A system. You have performers that will not be able to follow the mean as the mean goes up and I think that will be the corollary of how things [interruption] out. And what the mechanism for that is not understood.

Dr. Haywood: Let me just quickly comment on at least the first portion of that, and leave in abeyance for now the second portion as we continue to move forward collect. On the measurement activity, I agree wholeheartedly that it matters tremendously which measure we pick and we're all in agreement in how we're going to actually create a benchmark so we all understand what the actual metric is, and the impact that metric will particularly have. The World Health Organization, part of the reason, just so you know, part of the reason why US would do poorly under the system that they did is because we have over 45 million uninsured. And so that is one of the reasons you will, when you talk about the lack of access and that, we will continue to own those rank and irrespective of all these other issues underneath that that you throw in because what that says to the population outside the US is you're able to get into the right institution or the right provider, then this is the care that you would receive and they took a more global perspective saying, we're looking at the citizens in your particular country as a whole and how the level of quality of service that they receive, so to the extent that you don't have access to services, then you're probably going to do poorer than countries that actually allow particular access to services. So I think that's one of the biggest reasons why the US did poorly in that, and then on top of that, once you throw that in with the fact that they're looking at expenditures on top of that, then it's says not only are spending twice as much as some of these people, but you're not even covering as much, then we have a double whammy to be honest. So from that standpoint alone, before you even got to measures once you decided those were parameters that you wanted to use then we obviously weren't going to be in the top 10. But back to your original point, I agree wholeheartedly. That's part of the reason why we, I wanted to put this on the agenda and we continue to try to tell everyone about the National Quality Forum, that consensus process whereby it's open to the public. Anytime they do any particular measurement activity, as well as those counsel specifically from a consumer perspective, from a research perspective, from a provider or clinician perspective, as well as a purchase perspective. So that to the extent possible, we get as much input as we can. And then what we've done, at least at CMS what we've also done is for each individual setting, whether it be home health, nursing home, physicians or hospital, we've worked with the physician leadership or hospital leadership as well, so even though there's been an endorsement process, then we specifically work with that leadership as far as

implementation issues so that we can both get the best outcome as possible but also have processes in place where the reality is once you actually implement it, if there's any issues or miscommunications or concerns or anything of that nature, we have that feedback and feedback mechanism. And so we definitely anticipate that that will continue to evolve and continue to be one of the areas where we always will have to have agreement as to what that benchmark or that metric is.

Dr. Castellanos: Dr. O'Shea?

Dr. O'Shea: I have two concerns, just to think about and not to answer now. Could Pay for Performance potentially discourage physicians from caring for non-compliant patients? We've talked about this amongst ourselves, and so you have to be careful for what you initiate. If you're just going to look at the data that I give you, so I don't want that on mind, don't have time for you today. So we just got to look at that. The other one would be how does Pay for Performance programs ensure that the most up-to-date and accurate guidelines are being used. We sometimes even have data here from '02 and how can we actually get this data and how can we get it out to know that this is the benchmark that we're going to be measured at? So both those things concern me.

Dr. Haywood: Let me try to address both of those quickly. On the first prong, it's easy for me to say both as clinician and working as both areas that we agree wholeheartedly this is one of those when I had that bullet on that slide, I talked to you about unintended consequences of perverse incentives? This is one of the areas that we're also worked with, and there's different ways that people talked about trying to do that. One is if you lean more heavily on process measures, to the extent possible that takes care of a part of that process, because traditionally, a lot of those process measures are really looking at it from the standpoint whether or not you prescribed something or whether or not you did this from the clinician standpoint. But because we still want to get an outcome measurement as well, we also talked about ways in which you actually allow—and this happens pretty much on a physician side as well as hospital side—that patient to fall out of the denominator to be excluded, so in other words, what you do is have documentation, provided counseling, patient refused. So they fall out of the denominator to the extent possible. So those are the ways we've talked about really trying to do that to the extent possible and then we can look. Because to be honest, all the sudden, if you have 80% of your population is not compliant and fall out of your denominator, we may want to reinvestigate in how you're actually doing your documentation. But to the extent possible, that's what we've talked about. But again, that is

a conversation that we'll have, making certain that we're having that with those that are impacted so there's not like a one-sided decision that the government came up with that we did that collectively so that not only does it work from a policy standpoint, but when you actually try to implement it in your actual office, it's not all the sudden an additional task that someone has to remember and is problematic and burdensome and so then you start getting into issues about, well, it's just that the documentation was poor, because we're not really talking about buff and charts, we're talking about trying to get at the actual performance and being able to show that.

As to the second issue, up-to-date guidelines, you're part of that solution, too, to be honest. I think all the physicians are part of the solution. And the way that we've done it currently, is we worked with the guideline developers. And so the way the measures working, I gave you an example of at least one that we did and it was in the letter, went to the Annals of Internal Medicine, so you may have seen it last week, where [ace inhibitor orbs?] was the issue. So a lot of practitioners were already using orbs. Since it's physicians, I'm using abbreviated terms, because I feel I have the opportunity to do that in this format. So ace inhibitor orbs, we actually were able to say, OK, what are the guidelines? Work with the American College of Cardiology, work with the American Heart Association, CMS joint commission OREC, National Quality Forum, said OK, here's the situation. We know that this is what the trend is. We know that this is where the literature is. The two stories that come out that are particularly [?] study had already come and we said, are you changing your guidelines, and if so when, and see whether or not we can actually make the timing occur so that when we actually go forward that we already have it included. To be honest, at the time, the reason at the time, ACC and AHA were still going through that deliberative process and so their timing was a little off, by I think three or four months. And so what we did was say, fine, and as soon as it becomes available, then we'll go in and make an announcement, working with all those external stakeholders, saying that we're going to change the measurement to be consistent with that guideline. And so that's what we did and so now what you have is a January discharges, for all those patients that are in that data set, orbs is an option. And then what we're going to do later on this year is not only continue that to be an option, as far as being included and enumerated, but then we're going to allow for the opportunity through the data collection process is that you can bifurcate that such that is hospitals or clinician want to go back and see how many of my patients got ace inhibitor, how many got orbs, and what the break out is, we're going to have that opportunity. But that's one example, but we'll continue to work to rally try over this next year to have as full activity. And there's this process that we have that's called the measured manager

process that we're working closely with one of our quality improvement organizations in Arizona as well as Rand that helped us with building that activity. And we're hoping later this year that we'll be able to actually launch that and show the world how we actually anticipate having that continue dialog working with guideline development as well as individual practitioners as to concerns or issues they may have around implementation of particular measures.

Dr. Castellanos: Dr. McAneny?

Dr. McAneny: I'm relieved to hear you talk about not wanting to buff the charts on that because I look at this with a little trepidation having seen what's happened to nurses as they went through their quality measure, and it becomes a, you get your raise and you get your promotion depending on whether you have a care plan on the chart. I've never managed to read an entire nursing care plan. And they're not overwhelmingly valuable except for getting raises for nurses and promoting them and so I would hate to see this turn into a similar situation for physicians where we document like mad but don't have time to go to the bedside. The other concern I have is that the big macro brush of trying to get indicators which fit everybody may actually not serve a lot of populations particularly well. One of the best internists I know lives in Gallup, New Mexico. And his hemoglobin A1Cs are probably not very great in his population. But if you mention that a diet of fried bread is probably not the best thing, you're being culturally insensitive. So there are all these mitigating factors that occur. In our practice we decided we were going to look at some of the quality indicators and we're going to work with ASCO's quality program. We looked at it and we felt there are some things that are easy. Do you have the path report on the chart, do you have the tumor properly staged, do you, these seemed like obvious quality measures. And then as we came down and looked at further, two things occurred. One was that it's very disease specific. For example, if I'm seeing a cohort of elderly patients with metastatic lung cancer, a documented code status on the chart is a very important thing. If I'm seeing a bunch of 50-year-olds for aginate breast cancer and you walk in and go, hi how are you, do you want us to resuscitate you? It's sort of counter-productive. So one factor does not fit all and it needs to be very disease and practice specific, which has to be done on a very micro level, and probably has to be done voluntarily by the physicians and the people working in that clinic. The other thing that we found was that the EMR that we purchased, which was the best we could get when we bought it, some years ago, is now completely inadequate because it's not searchable for tumor size, staged, treatment, etc., and so for the last couple of years, I've been shopping EMRs. The most recent quote I got for the one that can

provide the functions that I want that would allow me to participate in this, for a practice of 9 physicians, they wanted $400,000. Well, let's see my Medicare drug money just went away, the Fee Schedule's going down, the SGR is going to nail us 30% over the next six years, where am I going to find $400,000? To put in an electronic medical record that I can then search and find all the stage two breast cancers and did they get their chemotherapy and how are they doing and by the way, how many of them are on Vioxx? I got to call them up and get them off it. So there's all these kind of issues that really are going to have to be addressed if you're going to bring that down to more than just a superficial level of, Do you have the path report on the chart?

Dr. Haywood: No, and you're articulating exactly some of the bears that we face as continue to try to work through this process. Thankfully, to the extent possible, none of those have come up as new to us, in a sense that we've actually started to map out stratas to address some of those. I think, all you probably know about Dr. David Brao and the Office for National Coordination of Health Information Technology and some of the activity that they have underway. And particularly part of the issues from the physician standpoint is concerns about quote unquote vaporware in the sense of here today, gone tomorrow, and us as federal entities encouraging you to go out and do that, and then you have concerns about wasting time and resources and all that and not being able to have anything to show for it at the end of the day. So there's activity underway right now to particularly address whether or not there's going to be a certification process, or accreditation process that allow you to know what your purchasing in the stance of functionality. So be encouraged that those conversations are heated up pretty quickly as to what that process is going to be about so that that minimum, you know you have a certain level of functionality, because it's been certified or accredited or something along those lines. On the issue of, this is similar to process and outcome, where there's a push and pull as it relates to how much you do at the disease level and how much you do at a larger level, and it's one of those things unfortunately where you're always saying, well, what can we do, what's the best to do because we think we should do both? On the one hand, to the extent possible, there is definitely measures where others have said well, you definitely could do certain structural or system measures and MedPac even mentioned structural measures, around whether if be EHRs or whether it be something along those lines. There's also work around ambulatory CAPs around the hospital side, or hospital CAPs, where you're looking at quality from the patient's perspective. And so that is another avenue in which you are having measurement activity that could be a more cross cutting, or broader. So those are either structural or system measure or patient perspectives of care. But then in reality,

once you start delving into it for the individual physicians, and when you start talking about peer groups and things of that nature, you do get into the weeds and details as to what are the disease or condition that we're going to look at and to the extent possible, how do we actually measure that performance? So you're not alone with those concerns at all, because we had those concerns with each activity. And one of the things that we continue to talk to societies as a whole, and we think probably in the near term, that we're going to be really pushing all the specialty societies to help us with is that issue, from the standpoint of you're the experts, you help us understand what you think is really the best view or look at performance from your individual entity. From your specialty society's viewpoint. You know this. So help us to really understand what you think the correct performance method should be from that vantage point.

Dr. Castellanos: Dr. Azocar?

Dr. Azocar: I was going to mention it was a great presentation with a lot of material. I was going to mention in the process of evaluating the performance, that those factors should be considered obviously, and I'm sure that you're including that demographics, [?] and culture because it's a big changes. And my other thing about when you mention about small practices, it would be based on information technology that would be a great help for the small practices to get some advice and endorsing basically about the kind of information technology that so it would be there two or three years. It would be the appropriate one. And I'm sure you have looked into that.

Dr. Haywood: Yes and I think we talked about EHR, so let me speak quickly for a second on demographic. This is another area I think that there is going to need to be more and more dialog because unfortunately it cuts both ways if you're not careful in the sense of you don't want to risk adjust away the problem, in the sense of risk adjusting it to the point where people don't focus on the particular community, the underserved or the racial and ethnic populations, but you also don't want to penalize people for focusing on that particular population. So we've continued to—and I know Robwood Johnson is looking at this particular area of working with us and Commonwealth Fund also has some areas interested in. So this is one of the areas that we specifically said that we were going to look at to make certain that there's not unintended consequences from that activity, so that people aren't discouraged to actually work in those particular environments to really improve their quality of care. Some have been encouraged to a standpoint of saying that they think that by moving toward this that you're actually finally recognizing and rewarding the activity that has taken place in the

sense of moving toward such that to the extent possible those that actually serve in that community ensuring some progress in those communities actually be rewarded at a higher rate. And those that have chosen to serve and who are affluent communities and more stabilized communities.

Dr. Castellanos: Dr. Senacore?

Dr. Senacore: I think one of the big things that was touched on earlier was the lack of an efficient way for a physician to transmit the key data elements that would go into a risk adjustment outcome measure. The DRG system, although it's not very robust, it does have process to have with and without complications, and a variety of code sets and that information is transmitted on the billing ticket, so when it goes on the UV-92, it gets transmitted to you. There's no way for me to transmit that in my office to say, or on an outpatient colonoscopy report that I was able to get the polyp out conascapically so I saved you having to pay for a colectomy. There's just not a good way to capture that kind of data and I think that's going to be the challenge in how you go forward with this system ultimately at the physician outpatient setting. The hospital side will be relatively easy over time to migrate to, but it's going to be a much bigger challenge to say what if my stroke rate as an internist is 5% of everyone else's? Well, you should be paying a lot more for me to manage hypertension, but what is that vehicle going to really look like out there when it hits the road?

Dr. Castellanos: Are there any other points? Anybody else wants to bring up? At this time, does the Council have any recommendations pertinent to this topic? We look forward to another report. Dr. Powers?

Dr. Powers: In the agenda booklet, there's a list from the AMA and I'm just going to use their recommendations: As CMS develops and implements Pay for Performance programs, these programs should remain in alignment with certain principles and guidelines developed by the AMA that are attached to the written statement, which is in the agenda book.

Dr. Castellanos: Is there any discussion on that? Could you read that back to us please?

Ms. Trevas: I have a copy, but it also refers to the written statement which obviously won't be captured in the recommendations. PPAC recommends that as CMS develops and implements Pay for Performance programs, these programs should remain in alignment with certain principles and guidelines developed by the AMA that are attached to our written statement.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? Dr. Powers?

Dr. Powers: CMS ensure that implementation of any quality improvement or Pay for Performance Program is premised on establishment of a reliable positive Medicare physician payment formula.

Dr. Castellanos: Can you repeat that please?

Ms. Trevas: PPAC recommends that CMS ensure that implementation of any quality improvement Pay for Performance Program is premised on establishment of a reliable positive Medicare physician payment formula.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? And the last, Dr. Powers? Is there one? Are there any other recommendations? Dr. McAneny?

Dr. McAneny: PPAC recommends that CMS as part of the Pay for Performance Plan develop criteria for electronic medical records and data collection sets to facilitate dissemination of IT technology among physician practices. It sounds like you're starting on it, but we need to be on board with it.

[off mike comment]

Dr. McAneny: PPAC recommends that CMS as part of the Pay for Performance Plan develop criteria for EMRs and data collection sets to facilitate dissemination of IT technology among physician practices.

Dr. Castellanos: Is there any discussion on that motion?

Dr. Powers: Is that not what the PEHRC is? P-E-H-R-C? There are already—CMS already has something in place, right?

[off mike comments]

Dr. McAneny: Oh.

Dr. Castellanos: My understanding is that Dr. McAneny wanted to make sure that was a recommendation by PPAC, even though they are working on it.

Dr. McAneny: And also to have it be part of the Pay for Performance Plan and not just as a separate initiative because I think that if you don't have the data sets that Dr. Senagore has been able to talk about and you can't produce them and you spend all your money buying a worthless CMR, you're never going to get to where you can prove that you're actually A. making the effort, and B. making any difference in outcomes.

Dr. Castellanos: Is there any further discussion? Could I ask you to read that back please?

Ms. Trevas: PPAC recommends that as part of the Pay for Performance Program, CMS develop criteria for electronic medical records and data collection sets to facilitate dissemination of information technology to physician practices.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? Are there any other recommendations? We thank you very much. It was a very enlightening discussion and I'm sure we're going to get to know you very very well. Thank you, Dr. Haywood. My understanding there's no organization that's making any oral presentation today, is that correct? There is a written testimony by the Alliance of Specialty Medicine, that's circulated and that's available.

[discussion off mike]

Dr. Castellanos: The chair would like to have about a five-minute break at this time.

Wrap Up/Recommendations.

Dr. Castellanos: Before we get into the Wrap up and Recommendations, I failed to mention or ask does the Council have any other recommendations they want to put forward to CMS at this time? Dr. McAneny?

Dr. McAneny: I'm sure that surprised everyone. I'd like to make one that says PPAC recommends that CMS include in the MAC contract, a mechanism for physician evaluation of service provided by the contractors, and for the use of these evaluation in determining improvement plans or even discontinuation of the contracts.

Mr. Kuhn: That will be part of the statement where provider satisfaction is a key component that we'll have as part of that.

Dr. McAneny: What I'm trying to do is go a little bit past just satisfaction, which is generally an evaluation, people remember what occurred in the last week, and whether the last phone call they made got answered properly and don't remember that 20 other phone calls the previous times. But actually some criteria that we would evaluate the MAC programs on from the physician perspective.

Mr. Kuhn: OK, thank you.

Dr. Castellanos: Is there any other discussion on this recommendation? May I ask you to repeat that, please?

Ms. Trevas: PPAC recommends that CMS include in the MAC contracts, a mechanism by which physicians can evaluate the service provided by contractors, and a mechanism to use the results of evaluation to determine improvement plans or discontinuation of the contract.

Dr. Castellanos: I'll call the question. All in favor? [Ays] Opposed? Are there any other recommendations that the Council wants to bring forth at this time for CMS? Dr. McAneny?

Dr. McAneny: To preface this one, in the OIG report on ASP, where they determined that everything was going to be just fine, there was also a statement in there that CMS was going to help oncologists find affordable drugs, which I thought was interesting. So I'd like to propose that PPAC recommends that since OIG stated that CMS would help oncologists find affordable drugs, that CMS report to PPAC some proposed mechanisms to accomplish this.

Dr. Castellanos: Is there any discussion on that? I would like to expand that, because these drugs not only affect oncology, but 20 other specialties to include urology. One of the points we have, and we asked last time on the PPAC recommendations for CMS to identify the different manufacturers and their costs. And we were, the answer there was that this data was privileged. I would like to add that as a friendly amendment that all our incident to drugs—

Dr. O'Shea: If they identify the manufacturers without giving us the costs, if it was the costs. If it's the numbers they can't release, they can still direct us to ones that they think are better.

Dr. McAneny: So oncologists and all affected providers?

Dr. Castellanos: Would it be possible to say that any practicing physician that is involved with incident to drugs or incident to their service?

Dr. McAneny: So all affected providers?

Dr. Castellanos: That's correct. Would that be acceptable?

Dr. McAneny: Should I restate it? PPAC recommends that since OIG stated that CMS would help oncologists—

Dr. Castellanos: No, you're changing that.

Dr. McAneny: What OIG stated was that they would help oncologists, but what we're trying to do is say OIG, just to leave the OIG part, we know what we're talking about. PPAC recommends that CMS help all affected providers find affordable drugs, and that CMS report to PPAC some proposed mechanism to accomplish this as was promised in the OIG report.

Dr. Castellanos: As was recommended in the—

Dr. McAneny: Well, the OIG just sort of made it sound like fact.

Mr. Kuhn: I'm just curious if you guys have a discussion on this, since the institution of ASP, have any of you changed your supply chain processes internally? What have you done, just curious?

Dr. Castellanos: I can tell you what we've done. We haven't changed it at all. Our ASP is basically the same because we're an LCA state. What we have done is not been able to provide some treatments to patients, specifically bladder drugs, bladder cancer drugs that we install in the bladder because it costs us more money, specifically Interferon and Mitamicin, the 40 mg dose. We lose money on that, so at this time, we have not been able to provide that to the patient unless the patient is willing to pay the difference.

Mr. Kuhn: But no new management practices?

Dr. Castellanos: No, we're still with LCA, so it really doesn't make any difference.

Dr. McAneny: But you're dealing mostly with Lupron and all the equivalents there, but for others, we have not entirely come to the conclusion of how we are going to manage with the people, for example, who don't have medigaps or who are duel eligibles when it comes to the expensive drugs, so we are putting in a pre-screening process now, which I have never done before in my life in 20 years of practicing oncology, to determine whether or not a patient's going to be eligible for a given drug, but if I, because we don't feel that it's ethical to have the doctor in front of the patient, be put in the position of saying, gee, if I give you Erbitex for your colon cancer, I can keep you alive another year, but it costs me $250,000 because you don't, either you don't have the money, or you aren't going to pay 20% of that. So with these new and incredibly expensive drugs, we're instituting several things. One is counseling of patients of what the drug costs to them is going to be and trying to do some of that ahead of time, which frankly feels terrible and leaves a bad taste in my mouth. And secondly, we're looking at various regiments and trying to have one group of our physicians determine whether or not the outcome of given regiments are equal, and then I or the billing people will figure out which one of those we can lose the least money on, and then select those regiments.

Mr. Kuhn: I guess what I was kind of looking for and curious about, is are you looking at your supply chain? Are you talking to GPOs with [?] organizations? Are you looking at different suppliers? What kind of, are you working with other physicians in order to get the benefit of more leverage in the marketplace? Things like that? Are those things going on?

Dr. McAneny: You have to be careful, or you go to jail for collusion. But yes, there are a couple drugs for example, Demcitabine comes to mind, that was immediately below water in terms of being able to afford the

drug. And so we went to the manufacturer and said, you've got to help us on this. We buy X amount of drugs from you, you've got to help us on this. And so they were able to do that. But as I talked to various practices around the country, they are trying to put pressure on, they are shopping hard to find cheaper drugs that are under ASP, but the problem is, it's as they succeed in doing that, then average selling price will move downward, which would be a good thing, except the, it's like the six sigma thing. The people who are on the top half of the drugs then will go out of business. And physicians being physicians, and not the best of businesspeople, what they'll figure out is, gee I didn't make any money this year, so I got to work harder. I got to see more patients. And they'll see more Medicare patients push more chemo and go further under water.

Mr. Kuhn: I guess what I'm driving at is when we saw the ASCO survey last year, it was interesting in that some very small practices were getting very good value on their purchasing of drugs. Others were not so good value. And I'm just wondering if the best practices are being disseminated to you all by your associations. How are you finding out how to improve your back office operations in order to change your supply chain efforts in order to be better purchasers in the marketplace with these new incentives that are put in place? And what I'm hearing is just, there's a variety of different things that you're looking at, but no real new strategies that have been deployed yet, if I hear right.

Dr. O'Shea: Catch as catch can.

Mr. Kuhn: OK, that's what I was wondering.

Dr. O'Shea: Societies will help you. There's not as much as you might think as of a connectedness with small provider groups within a small area.

Mr. Kuhn: OK, because I was trying to think how to respond to as I go back to staff and talk about the proposal you put on the table. I just want to check on that. But thank you. This has been helpful.

Dr. Castellanos: I can only say our society does not feel that that's their position, to try to help us identify manufacturers. We have a motion on the floor, could you repeat that?

Ms. Trevas: PPAC recommends that CMS help affected providers find affordable drugs, and that CMS report to PPAC some mechanism to accomplish this goal, which was recommended by the Office of the Inspector General.

Dr. Castellanos: Is that acceptable? [off mike discussion] I'll call the question. All in favor? [Ays] Opposed? Are there any other recommendations that we as PPAC want to present today to CMS? Seeing none and hearing none, we'll continue. Mr. Herb Kuhn will give the closing comments.

Mr. Kuhn: Just real brief because I don't want to stand in your way of getting to the airport and on your way home. Thank you again all for coming, for this first meeting for this new year. For this committee. I thank you again for your commitment, for your time to once again commit to four meetings this year and come to Washington to help us with this. Again, I appreciate Dr. Rapp, your past leadership, and welcome to CMS. Dr. Castellanos, thank you for stepping up to the plate, and for your leadership. I think this was a terrific meeting. I think there was a real dialog among staff, among one another with you all, and it was pretty obvious that I think that efforts to get you the materials sooner in the process has added to the richness of the discussion. I think you've looked at the materials, it's pretty obvious. You're coming well prepared, you spent the time to really think about this stuff, that will only benefit us and benefit you and your colleagues around the country in the long term. So thank you all very much. And safe travels home.

Dr. Castellanos: I think there's a couple comments I just want to make. I wanted to thank everybody here also for their presence. I think we've had a very productive meeting and rewarding, and I think we were able to provide CMS with some pretty good points that may help them with their doing their mission. I would like to thank the staff and the contractors for their skills and talent to make this meeting successful. This meeting requires a tremendous amount of work and coordination and communication, and we certainly, certainly appreciate that. The next Council meeting will be May 23rd, followed by August 22nd, and December 5th. Is there anything else before we close? Dr. McAneny?

Dr. McAneny: For future agenda items, one thing I'd really like to hear more about is the Recovery Audit Contracts and if we could put that on with some advance handouts, put that on the agenda item that would be very interesting.

Mr. Kuhn: Happy to help out in that regard. We'll, Ken's not here, but we'll make sure that's added to the list.

Dr. Castellanos: On that same topic, and I think it would be fair to bring up to you, I had mentioned to Dr. Simon, I'm sure that some of the PPAC members and myself included would like to have some input into the agenda. His feeling, and to paraphrase was that our basic responsibility was to advise CMS on the issues they

wanted discussed. I did go back through our charter, and some of the responsibilities of each member and the chair, and one of the responsibilities was that if any member did have a recommendation or wanting something discussed that they would bring it to the chair, and to Dr. Simon, and he felt that maybe if we did this, this could be brought to PRIT and it could be discussed under PRIT.

Mr. Kuhn: Yeah, there's a lot of different ways we can process things, whether it's through PRIT, whether it's open forum here, through the resolutions or the questions before it. I think there's a lot of different ways we can address things. Yes, please don't hold back. And if there's things that you want to see that you want to hear on that you want to have a chance to opine on, let us know, and we'll work our best to work with all of you to make sure we can do that.

Dr. Castellanos: Thank you. Again, thank you very much, we appreciate it. I think it was a very good meeting. Thank you.